First, Do No Harm

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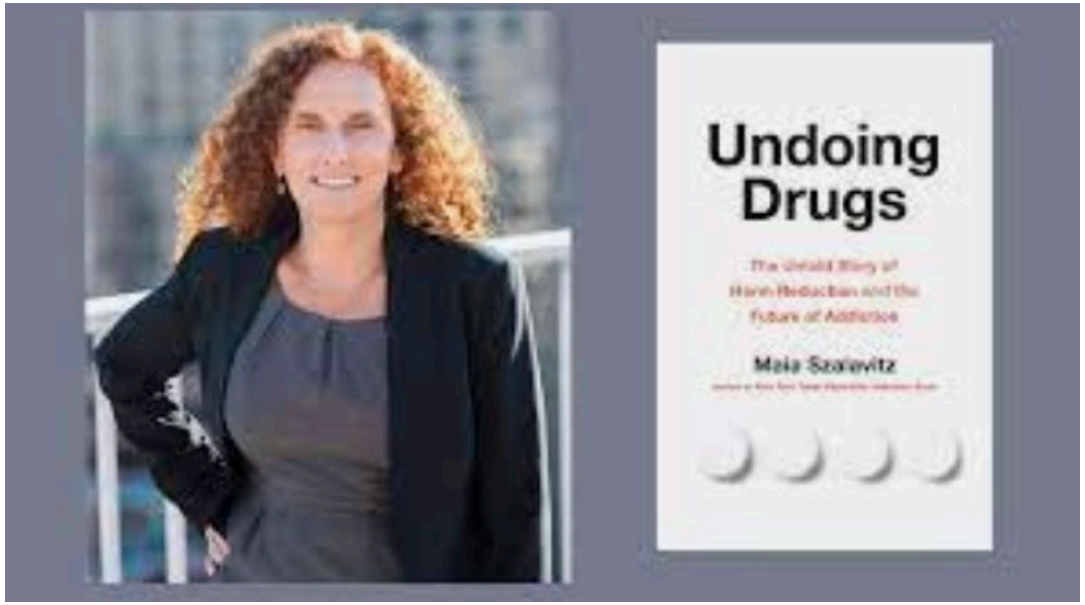
Executive Director, National Pain Advocacy Center.

NPAC takes no industry funding. Other disclosures: CDC Opioid Workgroup.

30-year career in health-focused human rights, previously at USDOJ, a primary drafter of Americans with Disabilities Act regs.



Harm Reduction

- Recognizes that people are going to engage in risky behavior – whether we want them to or not. So, the focus is on reducing harm vs. eliminating the behavior.

- In drug policy, harm reduction is the idea that we should stop people from getting hurt rather than solely targeting drug use.

Principles of Harm Reduction

- Offers pragmatic strategies to reduce negative consequences of drug use and promote individual and communal well-being
- Respects basic the human dignity of people who use drugs (PWUD)
- Calls for non-judgmental and non-coercive services
- Seeks to ensure that PWUD have a voice in programs & policies
- Is a social justice movement rooted in rights that recognizes that existing social inequities affect vulnerability to and capacity for managing harm

NATIONAL HARM REDUCTION COALITION

Intersection with Medical Ethics

CMA Code of Ethics emphasizes:

- Primary consideration of patient well-being
- Treating patients with dignity
- Taking all reasonable steps to prevent harm
- Refusing to support practices that violate human rights & to discriminate based on race, gender, medical condition, etc.
- Appropriate care, including physical comfort

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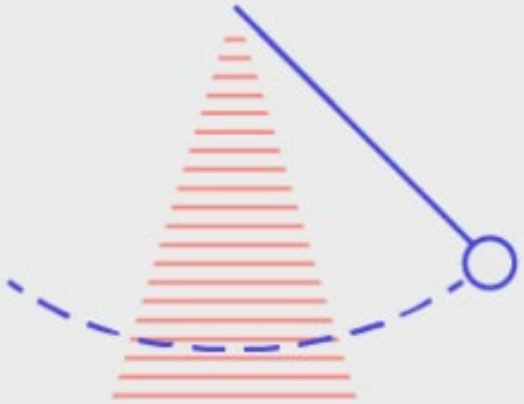
CANADIAN MEDICAL ASSOCIATION

Human Rights

- The United Nations and other human rights bodies consider access to pain management a human right.
- These rights are rooted in the international right to health; the right to be free from cruel, inhuman, & degrading treatment; & dignity, non-discrimination, & equality.
- Declaration of Montreal: Articles embrace non-discriminatory access.
- In the US and Canada, non-discriminatory access to care is covered by:
  - Americans with Disabilities Act; Section 504 of the Rehabilitation Act; Section 1557 of the Affordable Care Act.
  - Canadian Charter of Rights and Freedoms and Canadian Human Rights Act.

Pendulum Swing



1990s

Doctors encouraged to aggressively treat pain. **The risks of opioids are understated.** The result: rapid rise in prescribing of opioids.

2000s

Growing awareness that liberal prescribing has contributed to addiction and rising overdose deaths. **Public health agencies urge doctors to be more cautious when prescribing.**

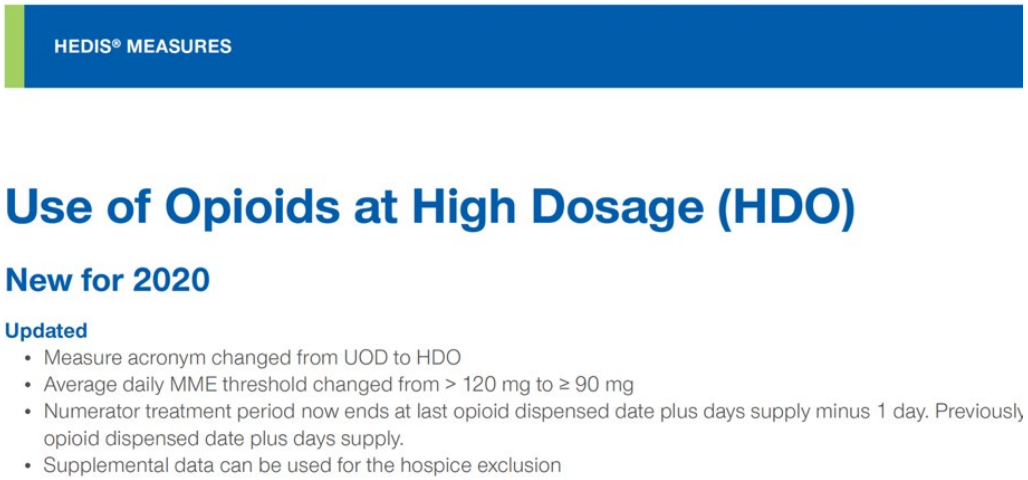
Today

Recommendations by public health agencies are implemented as strict laws and mandates, limiting access for those with legitimate need and cutting some—often abruptly—off necessary medications.

2016 CDC Guideline for Prescribing Opioids for Chronic Pain

Supply/dose thresholds to limit prescribing adopted as law or mandatory policy by:

- Majority of states.
- Federal lawmakers.
- NCQA, Quality Metric Agencies.
- Law Enforcement.
- Medical Boards.
- Payers.
- Health/Hospital Administrators/Systems.
- Pharmacies, Pharmacy Benefit Plans, etc.



HEDIS® MEASURES

Use of Opioids at High Dosage (HDO)

New for 2020

Updated

- Measure acronym changed from UOD to HDO
- Average daily MME threshold changed from > 120 mg to ≥ 90 mg
- Numerator treatment period now ends at last opioid dispensed date plus days supply minus 1 day. Previously, opioid dispensed date plus days supply.
- Supplemental data can be used for the hospice exclusion

Canadian Guideline

2017

CMAJ. 2017 May 8; 189(18): E659–E666.
doi: 10.1503/cmaj.170363

PMCID: PMC5422149
PMID: 28483845

Guideline for opioid therapy and chronic noncancer pain

Jason W. Busse, DC PhD, Samantha Craigie, MSc, David N. Juurlink, MD PhD, D. Norman Buckley, MD, Li Wang, PhD, Rachel J. Couban, MA MISt, Thomas Agoritsas, MD PhD, Elie A. Akl, MD PhD, Alonso Carrasco-Labra, DDS MSc, Lynn Cooper, BES, Chris Cull, Bruno R. da Costa, PT PhD, Joseph W. Frank, MD MPH, Gus Grant, AB LLB MD, Alfonso Iorio, MD PhD, Navindra Persaud, MD MSc, Sol Stern, MD, Peter Tugwell, MD MSc, Per Olav Vandvik, MD PhD, and Gordon H. Guyatt, MD MSc

- Optimization of nonopioid treatments
- When starting opioids – don't exceed 90 MED (w/o colleague consult) or 50 MED (informed consent/some patients may choose higher doses)
- Suggests tapering or discontinuing existing patients who are over 90 MED
- If unsuccessful, suggests referral to multidisciplinary clinics (accessibility issues.)

Clinician Uptake

Perceptions and Impact of the 2017 Canadian Guideline for Opioid Therapy and Chronic Noncancer Pain: A Cross-Sectional Study of Canadian Physicians

Jason W. Busse,[1,2,3,4] Joyce Douglas,[5] Tara S. Chauhan,[5] Bilal Kobeissi,[5] and Jeff Blackmer[5]

- 79% had amended/will amend their practices to conform to it
- More than 1/3 interpreted the GL as requiring mandatory tapering
- 51% had already engaged legacy patients in tapering
- 66% expressed resistance from patients
- 63% expressed concern re: lack of access ($/availability) to nonopioid treatment

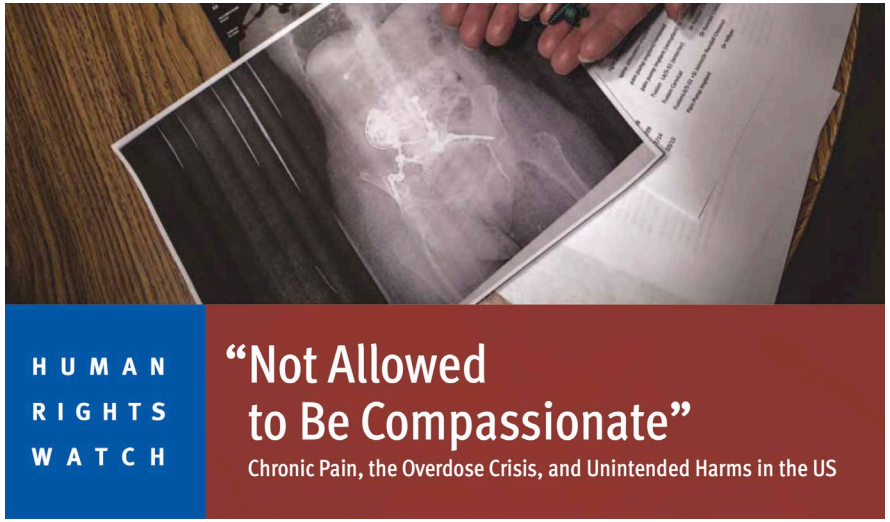
Concerns

cmaj jamc
CANADIAN MEDICAL ASSOCIATION JOURNAL | JOURNAL DE L'ASSOCIATION MÉDICALE CANADIENNE

CMAJ. 2018 Mar 12; 190(10): E300.
doi: 10.1503/cmaj.68662
PMCID: PMC5849452
PMID: 29530873

The 2017 Canadian opioid guideline: already time for an overhaul

The Canadian guideline's[1] key recommendations are flawed. Based on three small studies on highly select patients,[2] the guideline recommends tapering for all patients taking dosages at or above 90 mg morphine equivalents daily regardless of their clinical response to the opioid. - Kahan, Dubin, Clarke



Am J Law Med. 2020 May;46(2-3):297-310. doi: 10.1177/0098858820933500.

Opioid Prescribing and the Ethical Duty to *Do No Harm*

Kate M Nicholson [1], Deborah Hellman [2]

BC Guidelines

CPSBC released legally-enforceable minimum thresholds of professional behavior in relation to prescribing “high-risk” medications: opioids and sedatives.

In 2018, revised standards to clarify that providers should not discriminate, exclude or dismiss patients because of their use of opioids or sedatives.

Standards still require ”substantive evidence of exceptional need and benefit ” for doses over 90 MME; encourage tapering (though not abrupt) and discontinuation of either the opioid or sedative where they are co-prescribed.

Consequences: Access to Care

Pain Patients Who Take Opioids Can't Get in the Door at Half of Primary Care Clinics

"Secret shopper" study finds stigma is highest against those who say their last doctor stopped prescribing opioids to them.

(Lagisetty, PAIN 2021; Lagisetty, JAMA Netw. Open 2019)

81% are reluctant to treat people taking opioids. Quest Diagnostics, 2019.

Opioid Cessation

- An uptick in opioid discontinuation as a safety measure
- It is often abrupt
- It can lead to the need for emergency medical resources
- It *increases the risk of suicide and overdose by three to five-fold*

Studies on Discontinuation

Cessation of LTOT is on the rise (Fenton, JAMA Open Netw 2019)

Cessation is often abrupt (Neprash, JGIM 2021)

Cessation from high dose (>120 MME) typically occurred in 1 day, emergency care needed in half of cases (Mark, JSAT 2019)

Cessation is associated with 3x risk of OD, versus non-cessation (James, J Gen Int Med 2019)

Cessation in Oregon Medicaid associated with 3-5x elevated risk of suicide event (Hallvik, PAIN 2021)

In VA data, cessation associated with increased overdose and suicide (Oliva, BMJ 2020)

BC-based Canadian Study

Notes that US/CA engaged in systems-level efforts to reduce prescribing, but discontinuation is "largely unstudied."

Retrospective cohort study/patients on opioids 90 days.

◦ discontinuation increased the risk of overdose among people without OUD;

◦ stronger association among those with OUD;

◦ but tapering was associated with a decreased risk in those w/ OUD not on agonist therapy.

PLOS MEDICINE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

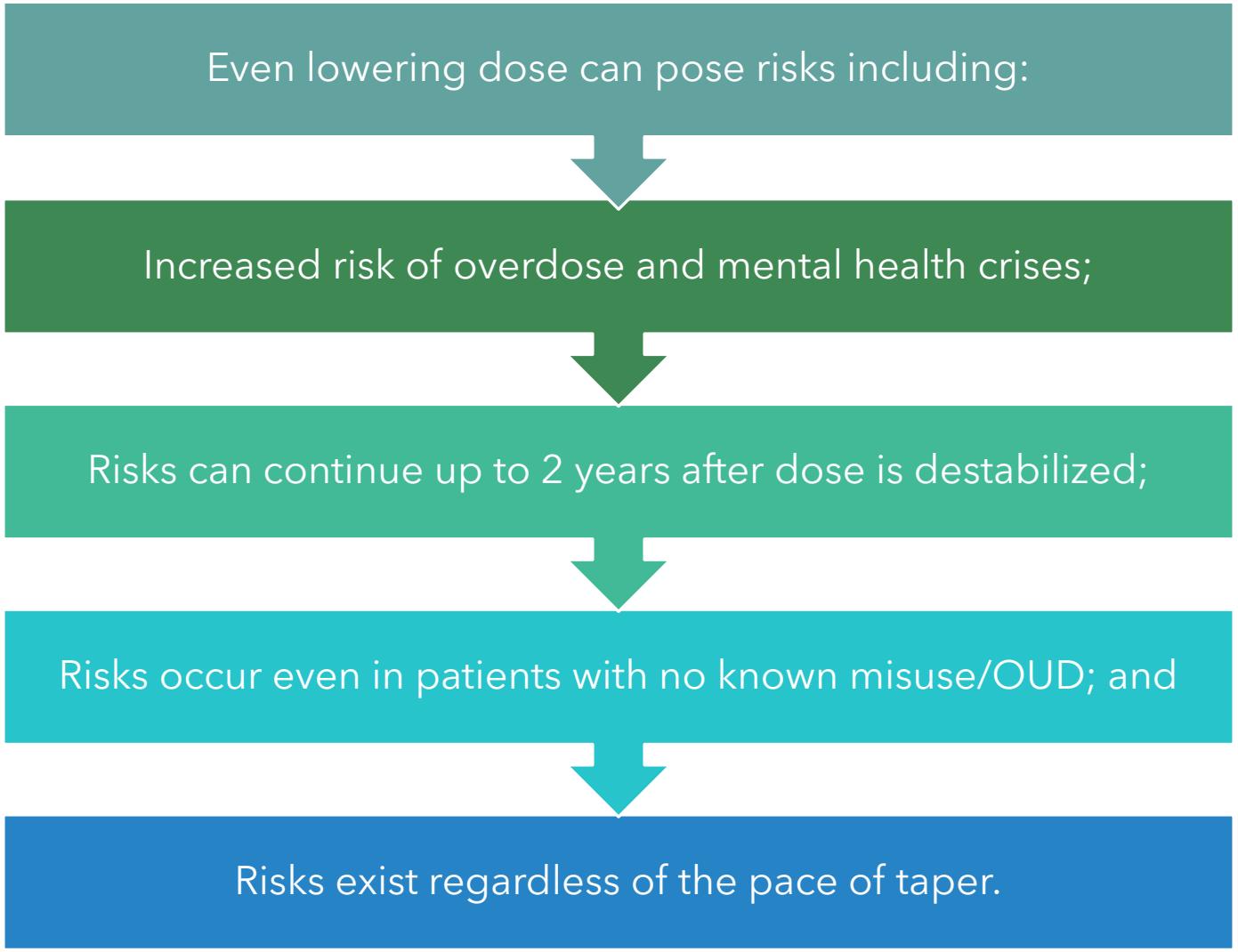
Discontinuation and tapering of prescribed opioids and risk of overdose among people on long-term opioid therapy for pain with and without opioid use disorder in British Columbia, Canada: A retrospective cohort study

Mary Clare Kennedy, Alexis Crabtree, Seonaid Nolan, Wing Yin Mok, Zishan Cui, Mei Chong, Amanda Slaunwhite, Lianping Ti

Published: December 1, 2022 • https://doi.org/10.1371/journal.pmed.1004123

Article | Authors | Metrics | Comments | Media Coverage

Even Reducing Dose Poses Risk



Studies on Dose Reduction

Just destabilizing dose (up or down) is associated with threefold increased OD risk. (Glanz, JAMA Netw. Open 2019)

Dose tapering is associated with mental health crises and overdose events. (Agnoli, JAMA 2021)

Higher incidence of overdose and mental health crisis continued two years post-taper. (Fenton, JAMA Netw. Open 2022)

Heightened risk of overdose and suicide in patients without OUD/misuse risk w/ no difference in outcome btw. abrupt or slow taper. (Larochelle, JAMA Netw. Open 2022)

Increased ER & hospitalization use, disruption in care, and lower medication adherence (for diabetes and hypertension). (Magnan, JAMA Netw. Open 2023)

Compounding Disadvantage

- **Racialized populations**: providers rate the pain of BIPOC people as less severe than that of their white counterparts, resulting in systematic undertreatment, even though studies suggest they likely experience greater pain. (false ideas equating biology with race).
- **Women**: are more likely to have their pain discounted or dismissed even though studies show they experience more pain; more comorbid conditions causing pain (the wandering uterus, hysteria).
- **Disability**: people with disabilities face heightened barriers to care and providers who substitute their judgment for that of the individuals (paternalism: takers, fakers, not makers).
- **LGBTQIA+** persons face heightened barriers to care, esp. transgender.

See, e.g., Hoffman K, *Proc Natl Acad Sci U S A*. 2016 Apr 19;113(16):4296-301; Losin, Woo, et al.. *Nature Hum Beh* 4: 517–530 (2020); Samulowitz A, *Pain Res. Manag*. 2018:6358624; https://nationalpain.org/resources-rights-and-disparities for many more.

Unequal access to medication

20 years of studies show that **Black and Hispanic patients are less likely to receive pain medication** for acute pain in the ER (Lee et al, 2019)

Black patients report higher average levels of pain but, in 90% of US healthcare systems, **receive significantly lower doses of pain medication** (Morden et al, 2021)

This inequity exists in end-of-life pain care in **Black older patients with cancer** (Enzinger et al, 2023)

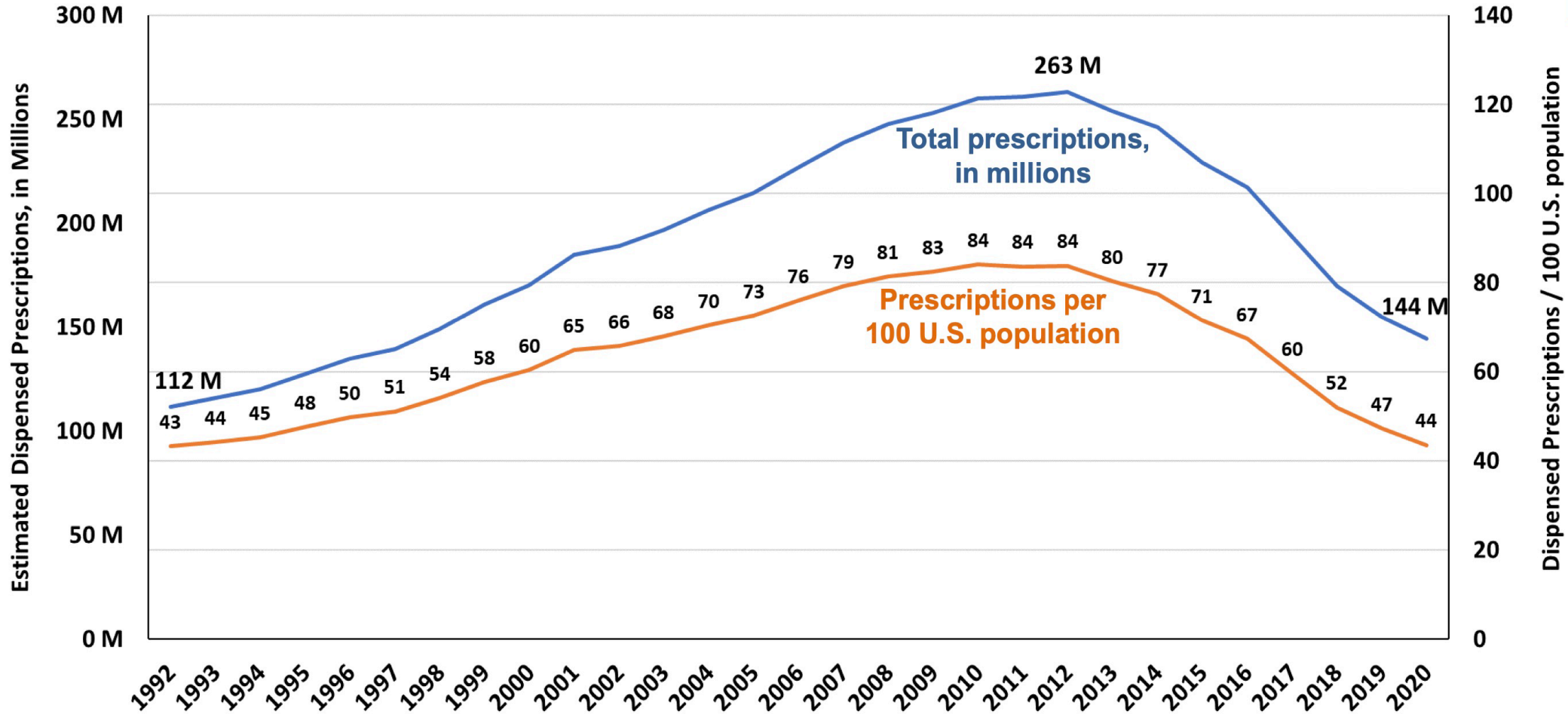
Some studies show a statistical correlation of **tapering with race and gender**. Fenton et al, 2019

Presumptions of Regulation

Presumption: decreasing prescribing → drop in overdoses

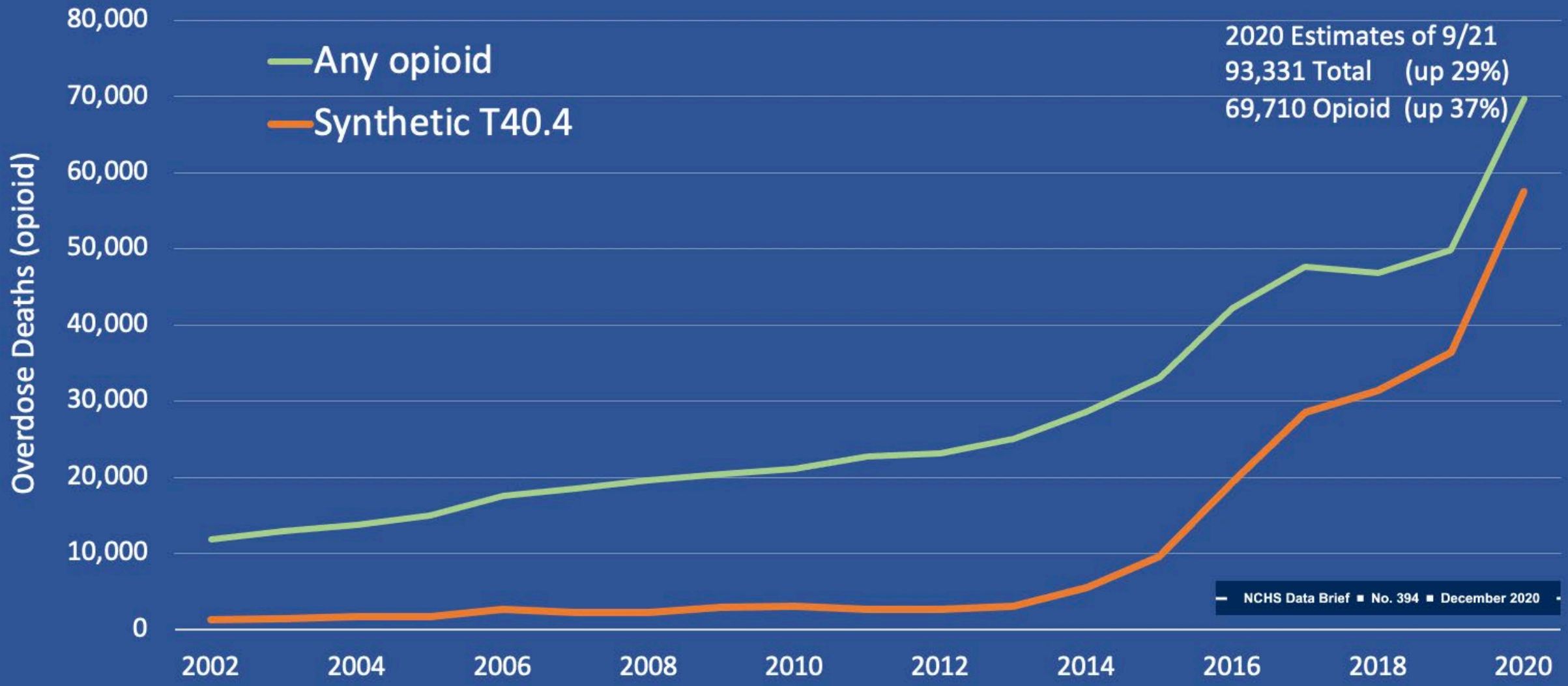
Reality: increasingly lethal street market → dangerous to incentivize use

Large Declines in Opioid Analgesic Prescriptions



Estimated opioid analgesic prescriptions dispensed from U.S. outpatient pharmacies, total and per 100 U.S. population, 1992–2020.
Source: IQVIA, National Prescription Audit™, time period 1992-2020. Data extracted July 2021. M = millions. Outpatient pharmacies included retail and mail-order pharmacies. Data included opioid analgesics only, excluding cough-cold products and medications to treat opioid use disorder. Any changes over time must be interpreted in the context of the changes in methodology, specifically during two trend breaks between 2016 and 2017 and between 2018 and 2019.

Opioid Overdose Deaths, USA (CDC/NVSS)



In Canada

Apparent opioid toxicity deaths in Canada since 2016

According to the Government of Canada, opioid toxicity deaths are 'caused by intoxication/toxicity (poisoning) resulting from substance use.'

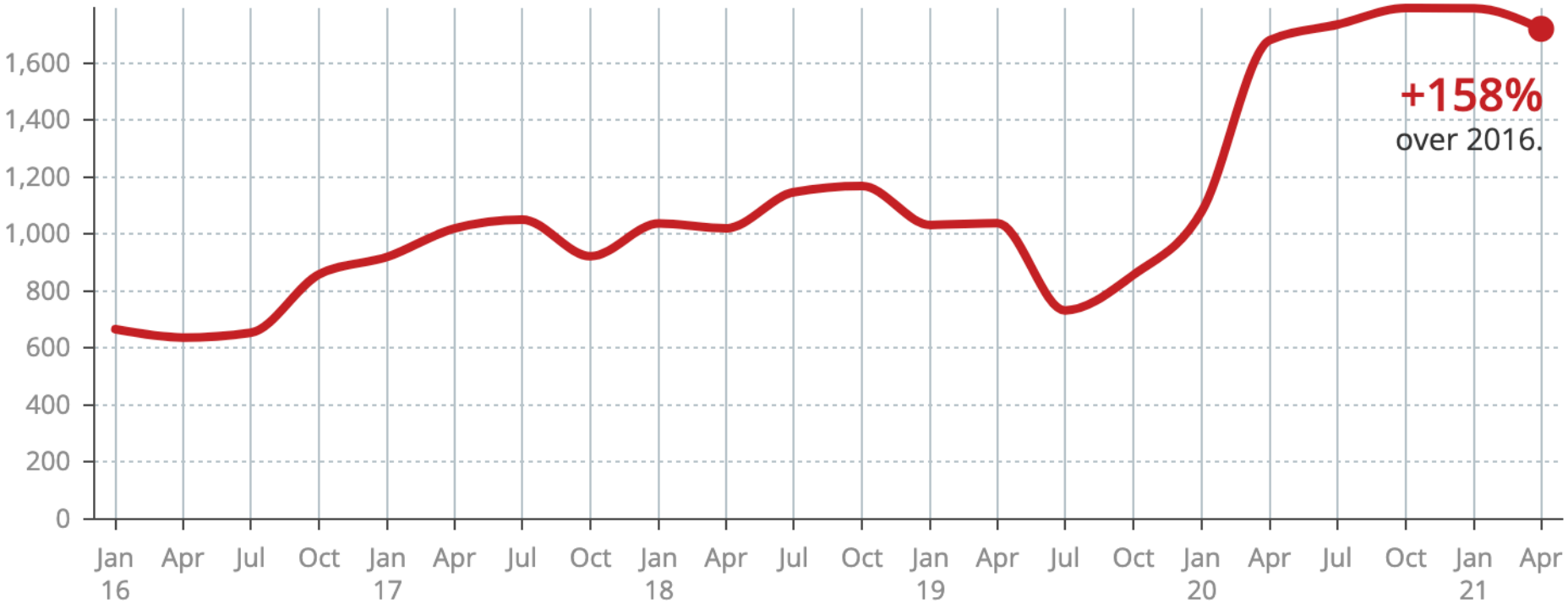


Chart: Dexter McMillan • Source: Government of Canada

CBC News

Query:

If our safety measures may do harm, given the duty to first do no harm, might harm reduction provide a path forward?

Is there a special duty to so-called legacy patients: those the healthcare system started on opioids?

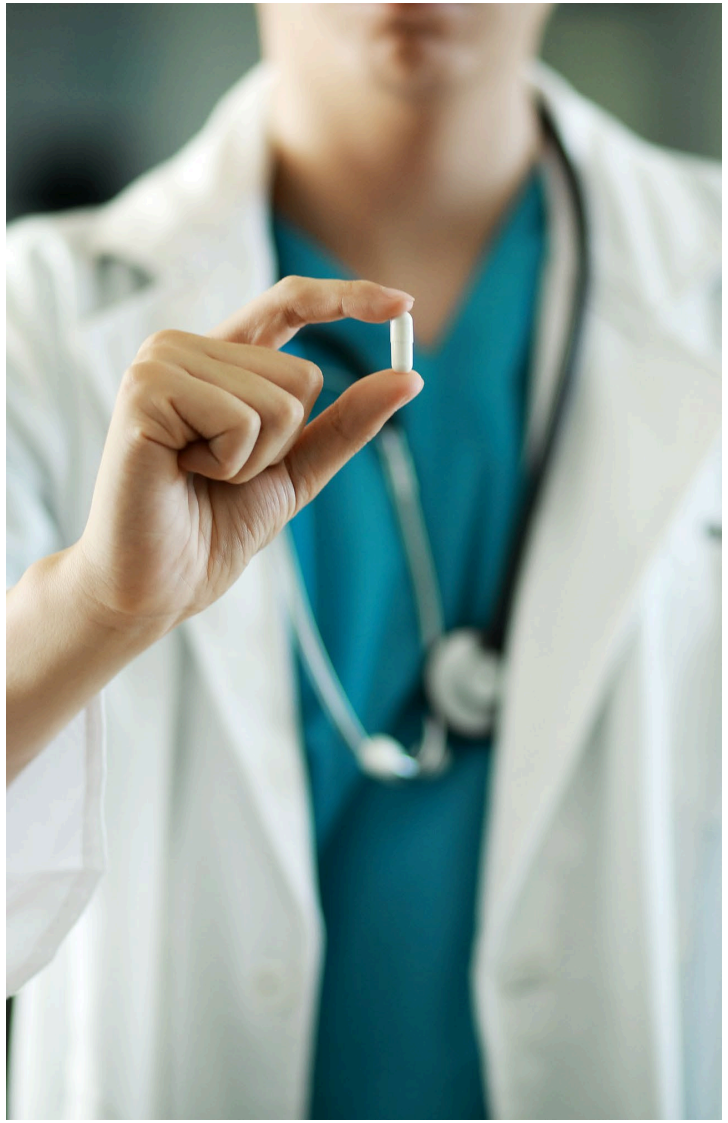
Canada

Note

* Reflects people who filled prescriptions at community pharmacies in Ontario, Manitoba, Saskatchewan and British Columbia.

In 2018, 17.6% of people prescribed opioids were using them long term, a decrease from 19.8% in 2013. About two-thirds of people on long-term therapy (62.8%) were prescribed strong opioids.[vii] The most common strong opioids prescribed to the study population on

Source: Canadian Institute for Health, Opioid Prescribing in Canada



U.S.

5 to 8 million on long-term opioids

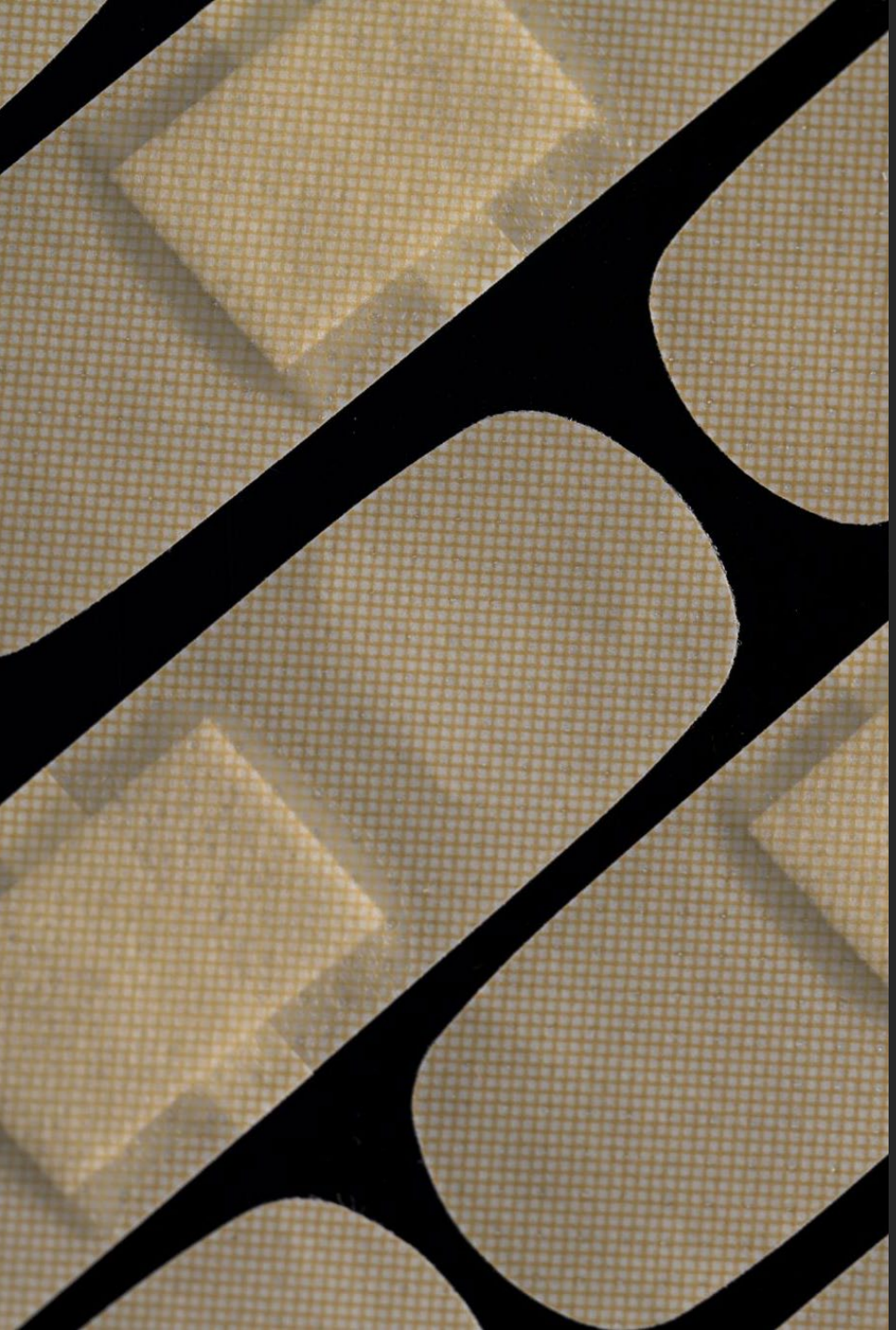
Kroenke, K,. *et al Pain Medicine 2019:* 20, 4: 724–735;Mojtabai R. *Pharmacoepidemiol Drug Saf.* 2018;27:526-534. (11 M as of 2014).

Pain Management As Harm Reduction

If harm reduction is about reducing harm by managing risks, meeting people where they are, keeping people healthy, safer, and alive, and according them voice and dignity,

If harm reduction is a response to supply-side responses undertaken in the name of safety that may –in fact– do harm,

Then people with pain who use opioids belong in the harm reduction spectrum.

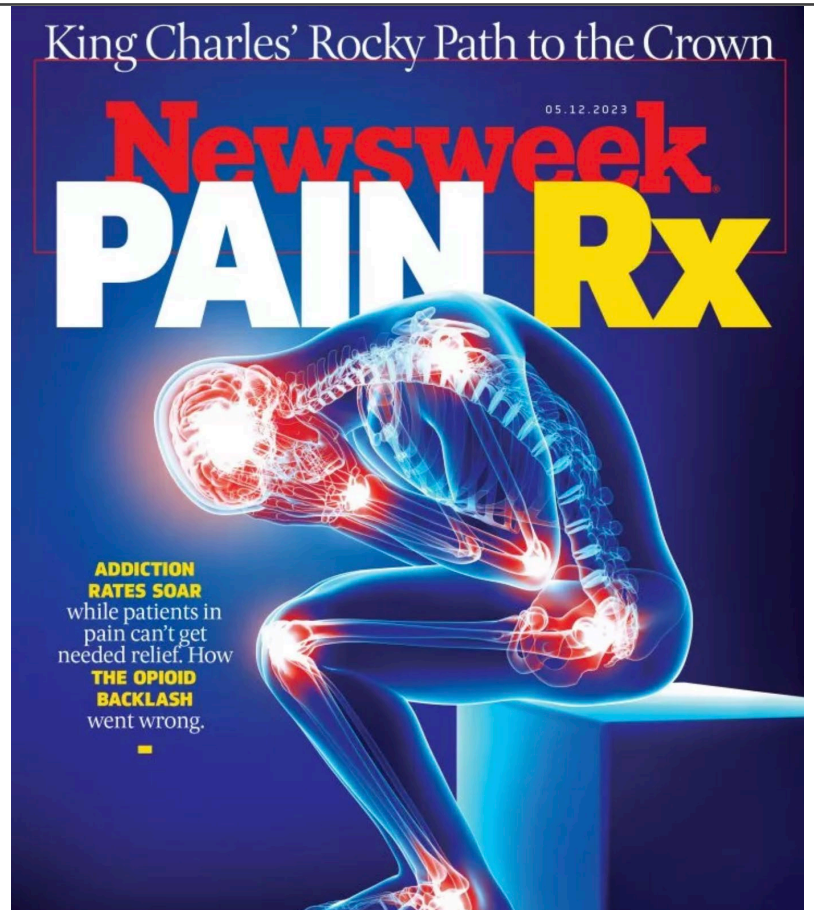


Applying Harm Reduction Strategies to Pain

Just as people who use injectable drugs tend to use clean needles when provided with them, people who do well with tapering are those with self-determination in the process. Darnall, et al. *JAMA internal medicine* vol. 178,5 (2018): 707-708.

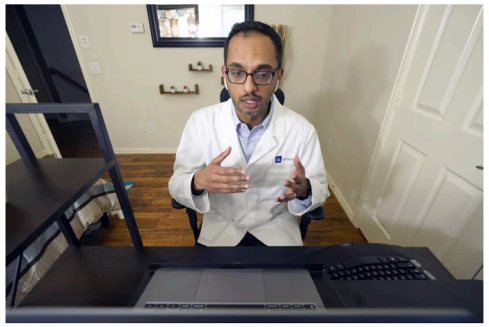
Also, consider → extending safer supply (retaining prescription medication, where appropriate); prescribing naloxone (vs. unsafe tapers); efforts to keep people in the healthcare system vs. abandoning them from it.

Today: Emerging Recognition



Los Angeles Times

Opinion: Don't curb opioid prescriptions through telemedicine. They're saving lives



During the COVID-19 pandemic, many patients who had struggled to access care finally found a way: through video appointments with providers such as Dr. Vibin Roy of Doctor on Demand. (LM Otero / Associated Press)

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After 18 years in prison, he took over his old L.A. gang. A string of murders followed

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How two friends sparked L.A.'s sushi obsession — and changed the way America eats

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Shangela, star of HBO's 'We're Here' and contestant on 'Drag Race,' accused of sexual assault

BY KATE M. NICHOLSON AND LEO BELETSKY

APRIL 15, 2023 3 AM PT

THE HEALTH 202

DEA seeks to temporarily extend virtual prescribing for controlled substances

Analysis by McKenzie Beard
with research by Rachel Roubein

May 3, 2023 at 8:07 a.m. EDT

Ongoing Policy Changes

In 2019 CDC issued a corrective. In 2022, new Guideline stressed individualization over strict limits.

Canadian GL is currently being revised.

U.S. States have enacted laws reversing hard limits or protecting patients from discrimination: Colorado bill. (Also, NH, MN, OK, ME, RI, AK, NV, AZ).

Rights-Based Interventions

In the US, it is illegal to discriminate based on medical conditions (which include people in recovery and people with pain) or the medication people take for their disability.

DOJ/Civil Rights did a series of cases prohibiting discrimination against people in treatment for an OUD & issued guidance on outpatient care, skilled nursing facilities, jails, and prisons (continued use of medication).