"What would be good care? Why can't we make it happen consistently?

A frameshift in the questions we ask

STEFAN G. KERTESZ, MD, MSC

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BIRMINGHAM VAMC OPIOID SAFETY, RISK MITIGATION, OPIOID ADVICE TEAM

Disclosures and my background

- I do not represent views of the US Government or State of Alabama
- No pharmaceutical grants, honoraria, contracts, history of such
- Past owned stock (Abbot, Merck <3%), sold in 2017.
- My wife has the same + J&J (<15% of her private assets)

- NIDA & VA-funded research: homeless, addiction, policy implementation (2002-->)

A thesis

- Let's note:
  - A systems-level decline in opioid reliance was necessary
  - I **won't** advocate (a) opioids on demand, (b) never tapering
- Thesis 1: good guidance can go wrong in practice:
  - Forced opioid reductions of a non-patient centered nature are "all but" mandated, absent protection for patients
  - Scholarly frameworks explain the "policy-to-practice problem"
- Thesis 2: I proceed from theory of patient care that is not just about whether we got "opioids right"
  - Health systems misapply guidance by neglecting the fundamentals

Walk with me - a request

- I will profile a **discrepancy** between good care and what is happening for patients who receive opioids long term
- Not crucial that we agree exactly on the size of that discrepancy
- In principle we don't want such discrepancies
- Let's look at **how** the discrepancy occurs

- Once we can explain what causes actual care to not resemble good care, then we can make better plans going forward

Good Care vis a vis opioid

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

- Reduce tendency to start opioids, offer better approaches
- If considering, scrutinize risks and benefits
- Exercise caution when escalating >50 or >90 MME
- For patients on opioids, evaluate harm vs benefit (#7)[1]
  - **No dose target**
  - **No mandated reductions**
- So what has happened?

Prescriptions fell

- Opioid Rx per capita 19% lower than in 2006, the earliest year posted on the CDC website

Something else happened

58 year old Jay Lawrence: dead
Google: Elizabeth Llorente, 2018

49 year old Kenyon Stewart: 367 mile drive. NP cannot continue.
Google: Terrence McCoy, 2018

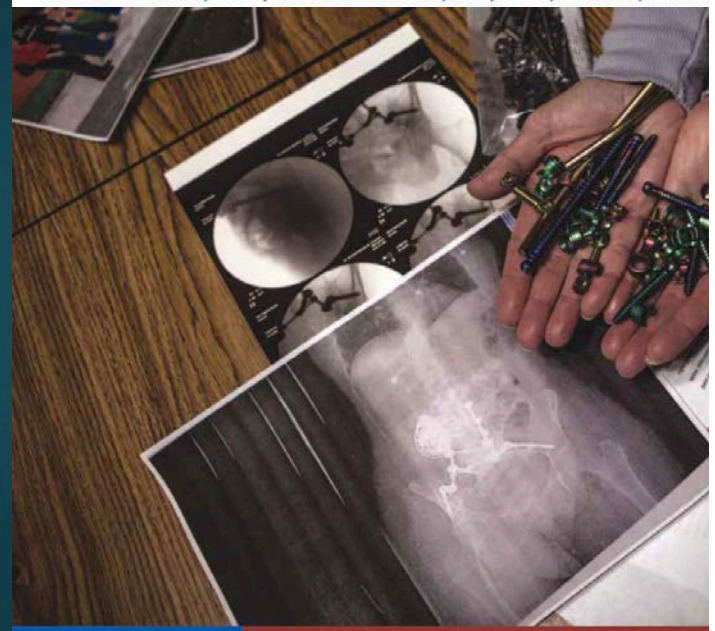
OXFORD ACADEMIC

Pain Medicine

Article Navigation

International Stakeholder Commu
Experts and Leaders Call for an Urg
Forced Opioid Tapering FREE

Beth D Darnall, PhD, David Juurlink, MD, PhD, FRCPC, FAAC



HUMAN RIGHTS WATCH

"Not Allowed to Be Compassionat

Chronic Pain, the Overdose Crisis, and Unintended Harms in the US

FDA

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The NEW ENGLAND JOURNAL of MEDICINE

Perspective

No Shortcuts to Safer Opioid Prescribing

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

April 24, 2019

But how did that all happen?

Was this a misunderstanding?

A lack of help from payers?

A regulatory thing?

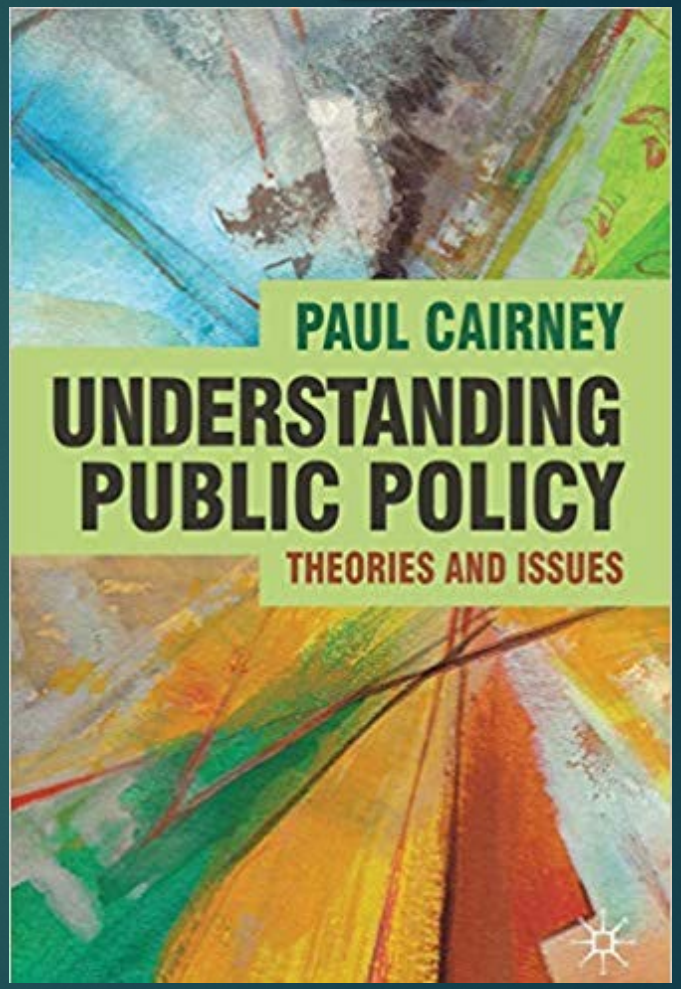
We have frameworks to assess health system changes!

A framework for understanding health system change

- Intervention of interest
- **Outer setting (e.g. policies emphasizing dose)**
- Inner setting (e.g. organizational resources)
- Processes (how the organization makes the change)

Policy scholarship insights

1. Policy isn't **ever** entirely rational
   - Leaders commit to solving before they understand
   - Overwhelming complexity→ shortcuts
2. Policy made not by one but many:
   - competing actors and agencies acting simultaneously
3. Policy monopolies establish stasis, until they give way



8 Do risks outweigh benefits of continuing OT?

Yes → 9 Proceed to Taper Module

No

10 Educate/re-educate on the following (see Sidebar C for talking points):

- Non-opioid management
- Self-management to improve function and quality of life
- Realistic expectations and limitations of medical treatment options
- Preferred treatment methods are non-pharmacotherapy and non-opioid pharmacotherapy
- New information on risks and lack of benefits of long-term OT

11 Are any of the following present?

- Prescribed opioid dose >90 mg MEDD
- Combined sedating medication that increases risk of adverse events (e.g., benzodiazepine)
- Patient non-participation in a comprehensive pain care plan
- Other indications for tapering (see Module B, Sidebar B)

Yes → 9 Proceed to Taper Module

No

A dose reduction plan that allows your patient to slowly and safely align with the CDC guidelines is required.

VA/DOD Guideline, 2017 (p.14)

POLICY ACTORS

Governmental

- Congress (SUPPORT Act, etc)
- HHS FDA
- Dept of Justice & DEA
- CMS Medicare D
- State laws & regs
- Medical boards

Framing Voices

- Leading Journalists
- Advocates
- Government speakers
- Litigation language
- Medical journals

Guidances & Metrics

- CDC
- VA/DoD & Canadian Guidelines
- NCQA, National Quality Forum

Payors & Other Entities

- Pharmacy chains
- Pharmacy Benefit Managers
- Hospital Administration (and VA)
- Any hospital or chain
- Malpractice policy

What has been missing:

- **Safe harbor for clinicians:** declared by trustworthy authorities
- **Institutional review, tracking, accountability** related to **any** harm after opioid stoppage
- In sum, policy actors:
  - offer conflicting messages
  - transfer liability to front-line doctors and patients
  - rarely offer tangible support to meet mandates
- On net: it's scary for health professionals and patients

Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment

journal homepage: www.elsevier.com/locate/jsat

Opioid medication discontinuation and risk of adverse opioid-related health care events

Tami L. Mark*, William Parish

RTI International, United States of America

- 494 Vermont Medicaid at >120 MME who discontinued, 2013-2017
- Median time to discontinuation: 1 day <21 days for 86%
- 49% had an "opioid-related hospitalization or ED visit"
- 60% had a "substance use disorder" diagnosis in record
- **<1% transitioned** to opioid use disorder medicine, in Vermont!

July 12, 2019

Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids

Pooja A. Lagisetty, MD, MSc[1,2,3]; Nathaniel Healy, BS[4]; Claire Garpestad, BS[1]; et al

» Author Affiliations | Article Information

JAMA Netw Open. 2019;2(7):e196928. doi:10.1001/jamanetworkopen.2019.6928

41% of 194 primary clinics surveyed

"were not willing to schedule an appointment for a new patient who was currently taking opioids for chronic pain"

No patient is safe if no doctor can assume their care

How should we interpret these events?

58 year old Jay Lawrence: dead
Google: Elizabeth Llorente, 2018

My son committed suicide 4 months after his docs took him off all pain meds. No meds or alcohol in his system when he shot himself to death on 8/27/2017. I knew right then the reason for his suicide. But, it goes on unrecognized by doctors and other officials, and his suicide autopsy mentioned nothing about pain meds. This will continue, suicides vastly increased until post medicinal suicides is recognized and accounted for.

Rick

300 mentions on social media. 85 that my team has linked to an identifiable person

Should we make causal claims about suicides?

- I suggest we adopt a patient safety framework: there are multiple factors meriting study and attention
- We are required to track and analyze many safety events in health care, so lets do it!

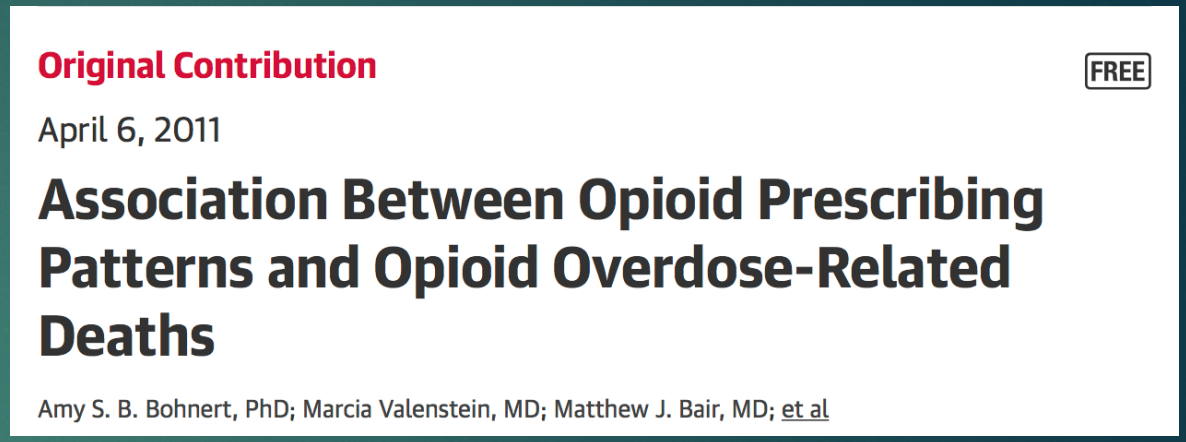
- For me, seeing inaction after safety problems were reported was an inflection point for my work

- And I wound up with a somewhat different scientific view, too…

A return toward clinical evidence

Why might one be skeptical of a focus on dose reduction as the primary path to patient safety?

Dose is relevant but overemphasized in risk of death


Original Contribution

FREE

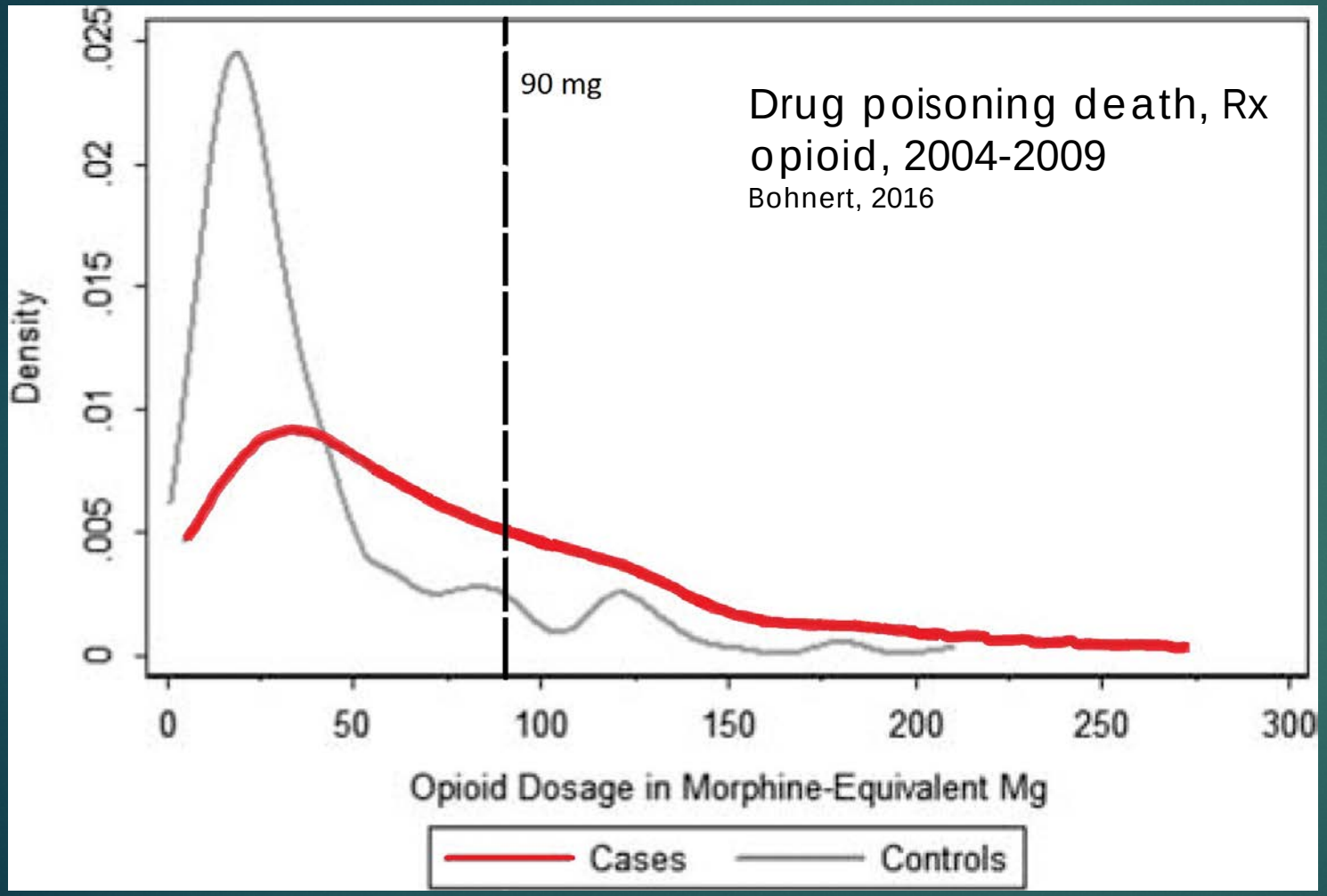
April 6, 2011

Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths

Amy S. B. Bohnert, PhD; Marcia Valenstein, MD; Matthew J. Bair, MD; et al

- Dose: Higher risk of death
  - Higher dose (>100 MME, 7 times higher risk)
- Age & Race: Lower risk of death
  - Age 18-29 : 5 times higher than age 60-69
  - Whites: 3 times the risk of Blacks
- We could apply this as if every association was causal
- Accept factors, as important as dose, visible in clinic that don't pop out of databases
- Some are not measured but correlated with dose, race and age. Perhaps we see these things and can respond to them

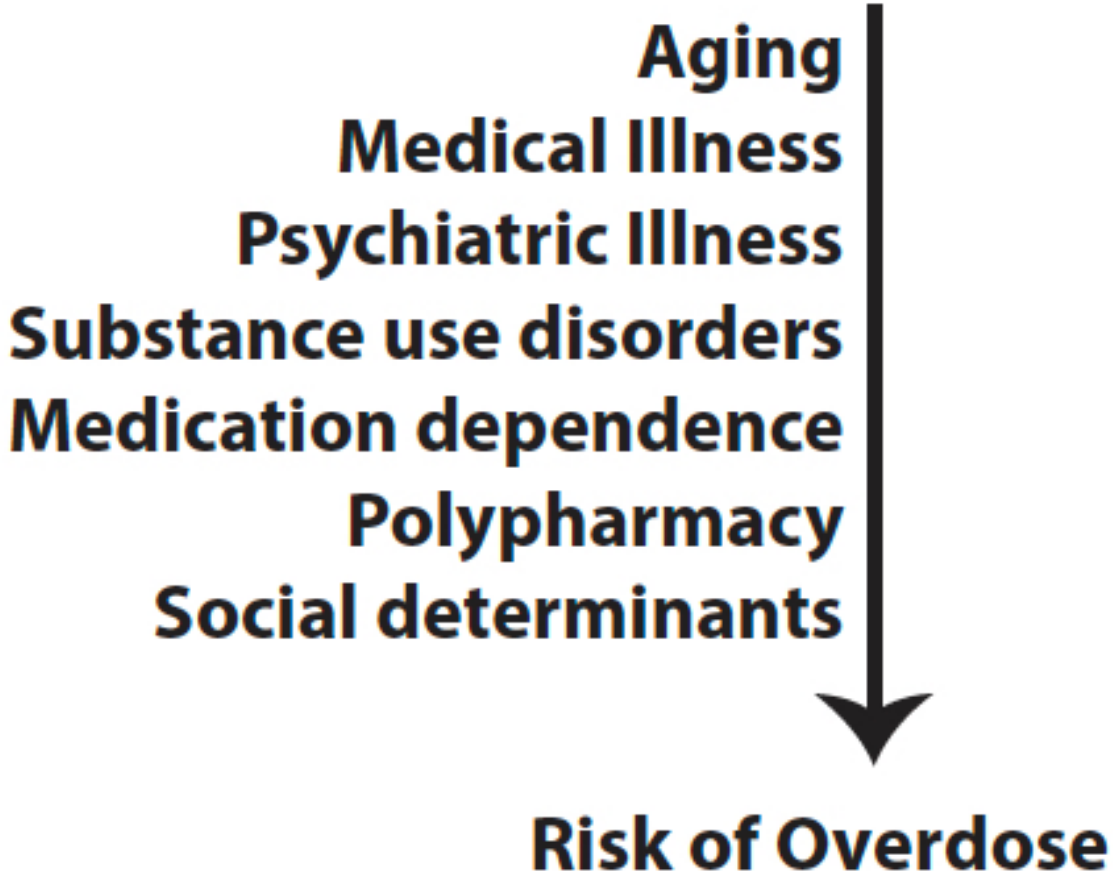
To save lives, go where the deaths are



At my hospital today, **<2% of chronic opioid recipients are at >100 MME**

From 2010-16 VA **opioid Rx down 52%**

Rx opioid OD's **unchanged** (Lin et al. 2016)



Sources:

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Who is the ***person*** we wish to help and what is our model for care of a ***person with (often) multiple morbidities***?

Aging
Medical Illness
Psychiatric Illness
Substance use disorders
Medication dependence
Polypharmacy
Social determinants

Risk of Overdose

Comprehensive practices (in Primary Care):
patient centered, reduce risks, focus on function

- Assess full history (e.g. social history, trauma, self-efficacy, substances)
- Function: "what do you each day?" "what holds you back?"
- Craft a new pain narrative, the brain's role, recalibrating goals
- Introduce new understanding of risk and of medications
- Assess the manageability of patient's behavior in relation to my team

- I am permitted time to do this because of my clinic
- I take time to develop trust
- This should be compensated work. Repeat that. Compensated.

Opioid-related practices:

patient centered, reduce risks, focus on function

- If stable → discuss taper vs monitoring
- Emphasis on behavioral activation, exercise, sleep, social relationships and social burdens
- If tapering: "we will *reverse* if we see harm"
- If poorly functioning, consider:
  - intensified monitoring + *leverage* to rehabilitative activity
  - switch to buprenorphine absent consent
  - try to find choices the patient can make

STATNews, 2019
With consent

- I see taper as sometimes helpful, **and** with risk of adverse outcome. I have required it, but rarely

My reasoning on opioid taper

- Any doctor who thinks a patient is harmed has **authority**, as I see it, to change the treatment (that includes **taper** with or without consent)
- This entails **risk** and potential **benefit**
- So far we **lack prospective evidence** that a patient is made safer by dose reduction (the history of medical reversals teaches caution)
  - Estrogen post-menopause, Lidocaine after MI, Hemoglobin a1c<7%
- The "OD" event in Rx populations reflects a **web of risks**
- We can make that web **worse with taper,** particularly if it is:
  - Carried out in a way that is threatening to the patient
  - Carried out non-expertly or without resources

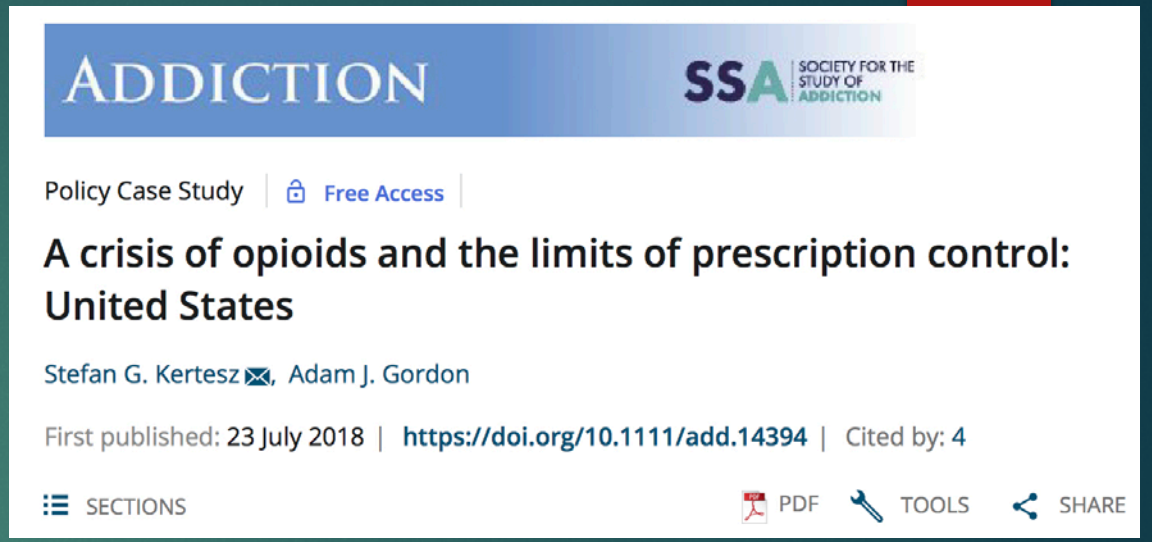
What I think will help

- Any entity urging pain care changes must track **patient-level** outcomes (e.g. life, death, disability)
- **Care** is not for an **opioid**, but for a **person** with a life history
- Consider **both** taper and intensified monitoring as viable

- We must tangibly support **protection** of clinical relationships
  - Mentoring & guidance for prescribers
  - Safe harbor for prescribers
  - Access to mental & complementary health
  - Repudiation of metrics and tools that reward abandonment

Feedback?

- https://www.surveymonkey.com/r/GBLNVKK



ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

Policy Case Study | Free Access

A crisis of opioids and the limits of prescription control: United States

Stefan G. Kertesz, Adam J. Gordon

First published: 23 July 2018 | https://doi.org/10.1111/add.14394 | Cited by: 4

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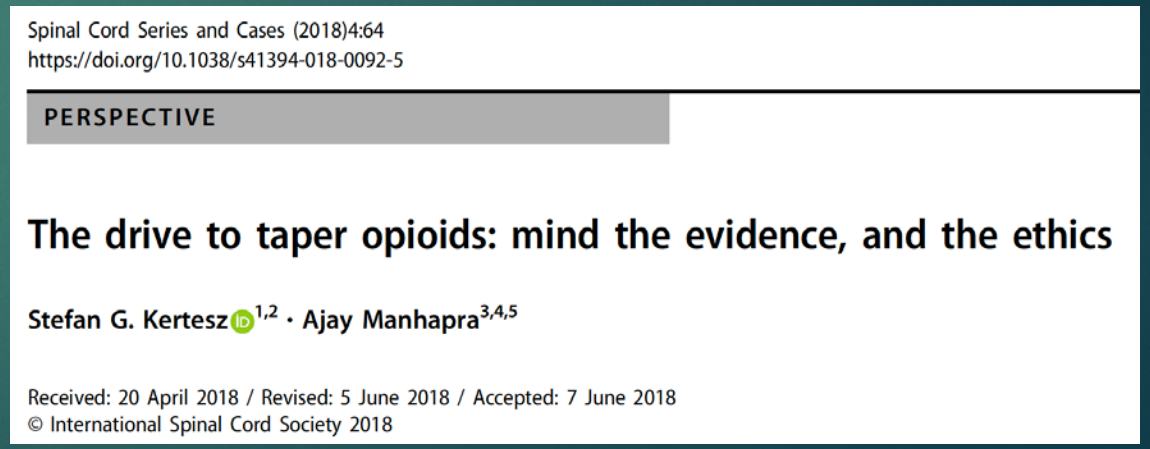

Spinal Cord Series and Cases (2018)4:64
https://doi.org/10.1038/s41394-018-0092-5

PERSPECTIVE

The drive to taper opioids: mind the evidence, and the ethics

Stefan G. Kertesz[1,2] · Ajay Manhapra[3,4,5]

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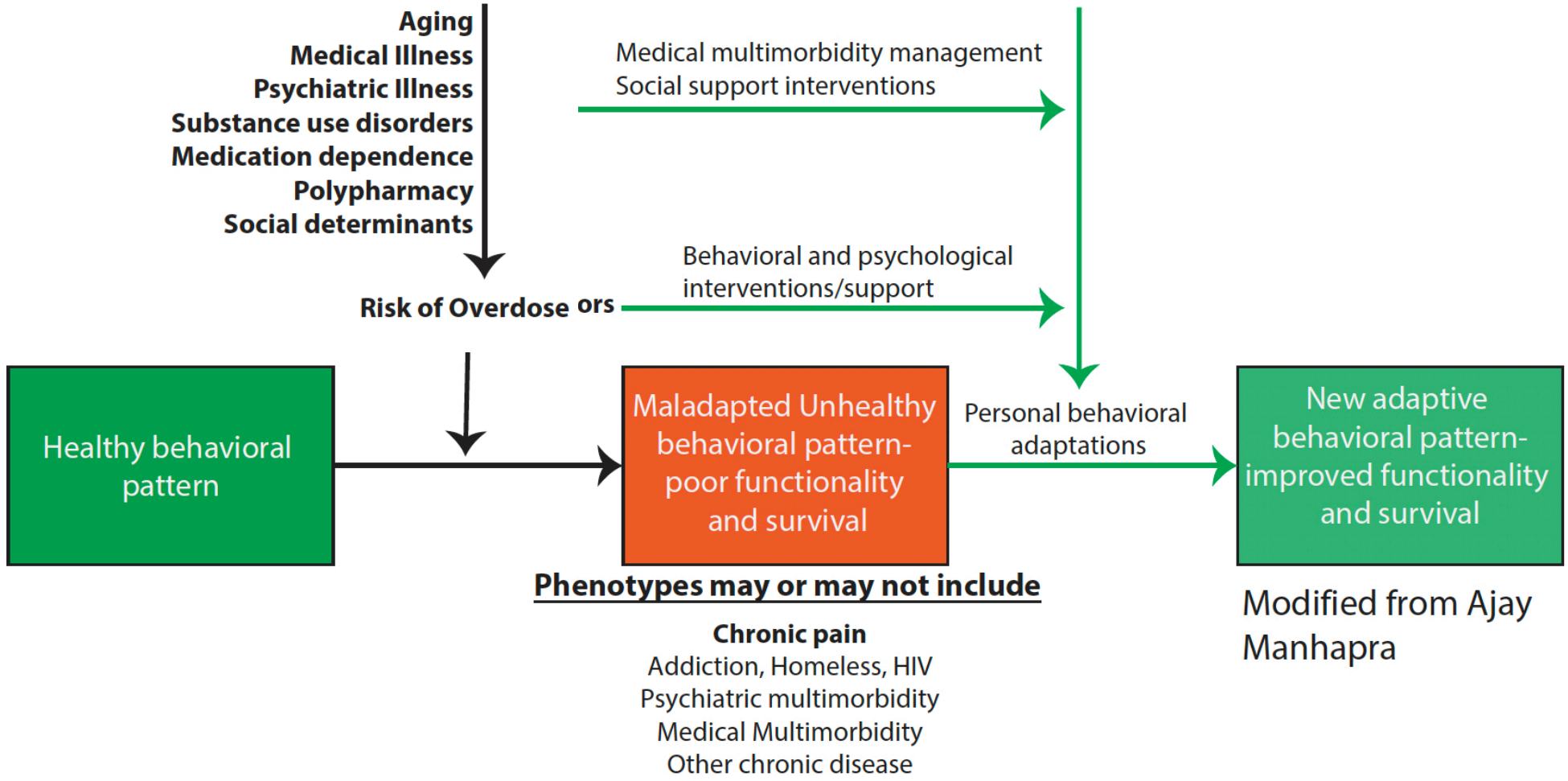
Recovery Oriented Model of Care For Multimorbidity Phenotypes Among Vulnerable Veterans



Modified from Ajay Manhapra