THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

U.S. Department of Veterans Affairs

"Opioid deprescribing as a (de-)Implementation Science Challenge

NIH Helping to End Addiction Long-term (HEAL)

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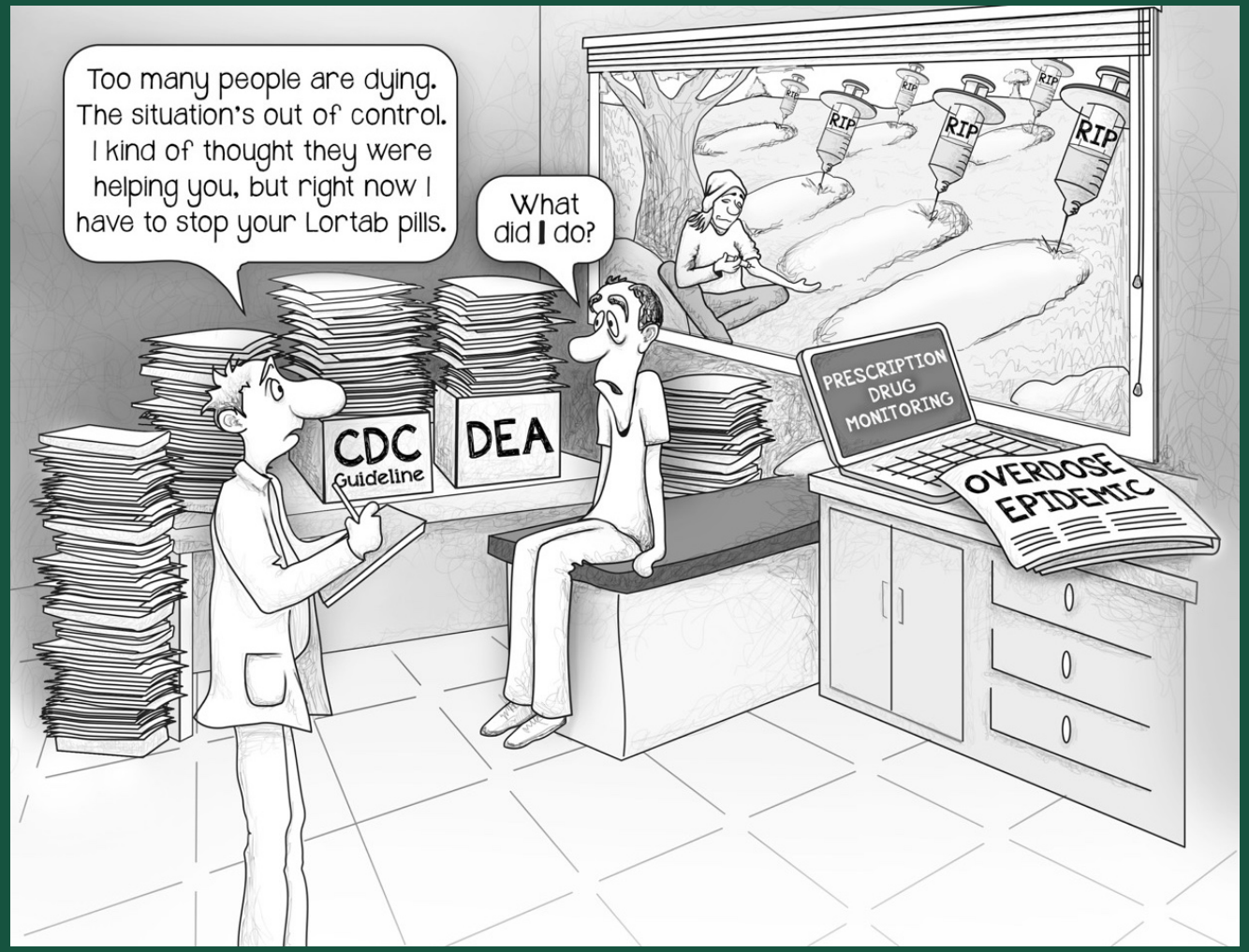
Disclosures and my background

- I do not represent my government employers
- No pharmaceutical grants, honoraria, or business with them
- I own shares of Thermo Fisher, CVS Health, Zimmer Biomedical

- I'm an internist and addiction medicine physician
- Focused on vulnerable populations with research funded by NIH and VA HSR&D since 2002



Kertesz S. G. **Turning the tide or riptide? The changing opioid epidemic**. Subst Abuse 2017; 38: 3–8. doi: 10.1080/08897077.2016.1261070

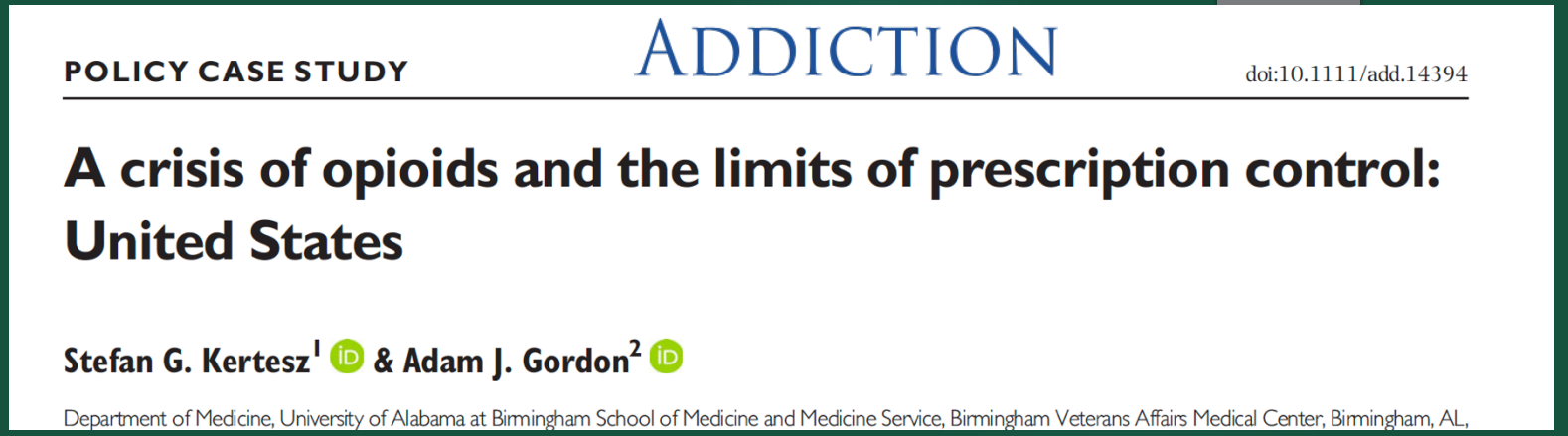
This is a fraught moment. A public health concern is involved.

My thesis

- ~10 million patients on long-term opioids for pain[1]
- Stopping or tapering is a **clinical** intervention (for a person)
  - Clinically: we must move toward rigorous assessment of what accounts for **both** good **and** bad outcomes
- When health systems act to cause stoppage or tapering of opioids, that is a form of **de-implementation** (for the system)
  - De-implementation can be done well or poorly
  - We have a framework for studying implementation **and** de-implementation (Consolidated Framework Implementation Research)

1. Derived from: Mojtabai. Pharmacoepidemiol Drug Saf. 2018; 10.1002/pds.4278

The context



POLICY CASE STUDY ADDICTION doi:10.1111/add.14394

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

Stefan G. Kertesz[1] & Adam J. Gordon[2]

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Rx, OUD & deaths rose

- Rose through 2012
- Per NESARC
  - Rx OUD (0.4% -> 0.8%)
  - Heroin OUD (0.2% -> 0.7%)
  - 53% whites "started with" pills[2]

Rx declined

- Rx decline began in 2012
- Overdoses persisted
- An "imbalance"
  - strong Rx control
  - weak pain and addiction care
- Systematic opioid reduction is de-implementation

1) Kertesz/Gordon. Addiction. 2019; doi.org/10.1111/add.14394
2) Martins. JAMA Psy. 2017; doi.org10.1001/jamapsychiatry.2017.0113

"De-implementation"

- "Reducing or stopping services or practices that are ineffective, unproven, harmful, overused or inappropriate"[1]
- Prasad's categories. Practices that are[2]
  - Contradicted
  - Unproven
  - Novel interventions without data

- But, de-implementation "fits" easier on some treatments than others

1. Norton et al. Impl Sci. 2017; doi.org/10.1186/s13012-017-0655-z
2. Prasad & Ioannadis. Impl Sci. 2014; doi.org/10.1186/1748-5908-9-1

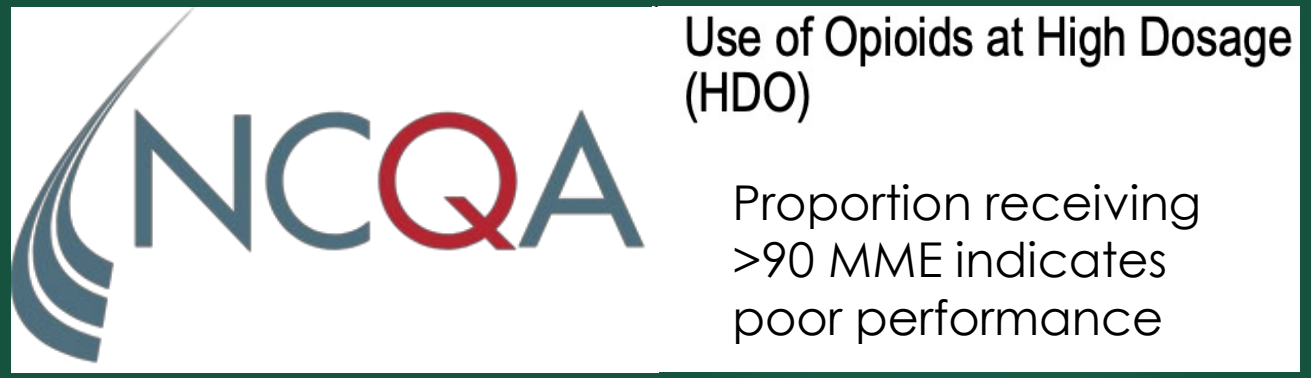
De-implementation: a trickier fit for some problems than others

- Antibiotics for routine URI
  - A discrete **diagnosis**
    - virus, runny nose, cough
  - Stakes low
  - Every doctor trained
  - Antibiotics **ineffective**
- De-implementation: "not starting"

- Opioids for severe chronic pain
  - an **experience:** peripheral + central drivers
    - Chronic pain sits in a rehabilitation framework of multimorbidity
  - Stakes high
  - Doctors **not** trained
  - Opioids have a **modest effect**, on **average**
- De-implementation: "not starting" or "tapering" or "stopping"?

De-implementation applies **anyway**

MME 3 x higher in 2015 than 1999
Major agency declares a failure to attain goals

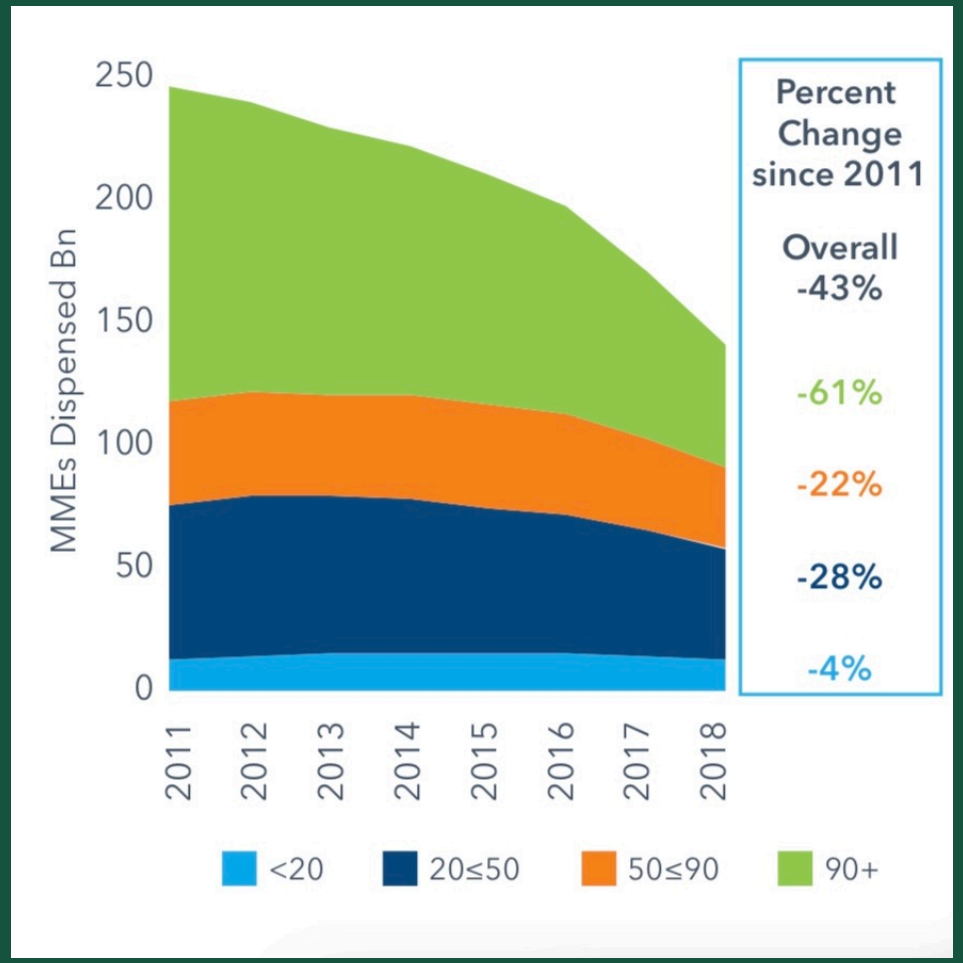


Establishes a metric that affects both monetary reimbursement and quality ratings

Total MME overall, and in daily dose, are central
But 5% of recipients consume 59% of MME[1]
Long-term recipients are the de facto central target

1) Sun & Jena. Ann Intern Med. 2017. doi: 10.7326/M17-1408

De-implementation is happening



- Rx per capita in 2018 19% lower than in 2006 (NQVIA/CDC)
- Decreases are more concentrated for persons at higher dose & worse pain[1]
- Our focus: ~10 million currently on opioids[2]
- All emphasis from payers and metrics is on reduction for them and preventing more of them

1. Olfson, Health Affairs. 2020; 10.1377/hlthaff.2019.00783
2. Mojtabai. Pharmacoepidemiol Drug Saf. 2018; 10.1002/pds.4278

Taper's Clinical Promise

40 studies with patient outcomes

- 5 were RCTs (total N=261 patients)
- Most short-term & **voluntary**
- **None** rated "good quality"
- Improvements in pain & pain related function
- **But:** No data on mandates, few data on harms such as suicide or transition to illicit use transition
- New trials, also with volunteers, ongoing

Frank et al. Annals of Internal Medicine. August 1, 2017

Taper's Clinical Troubles

Three declarations of 2019

- FDA Warning (April, 2019)
- CDC Clarification (April, 2019)
- HHS Guidance (October, 2019)

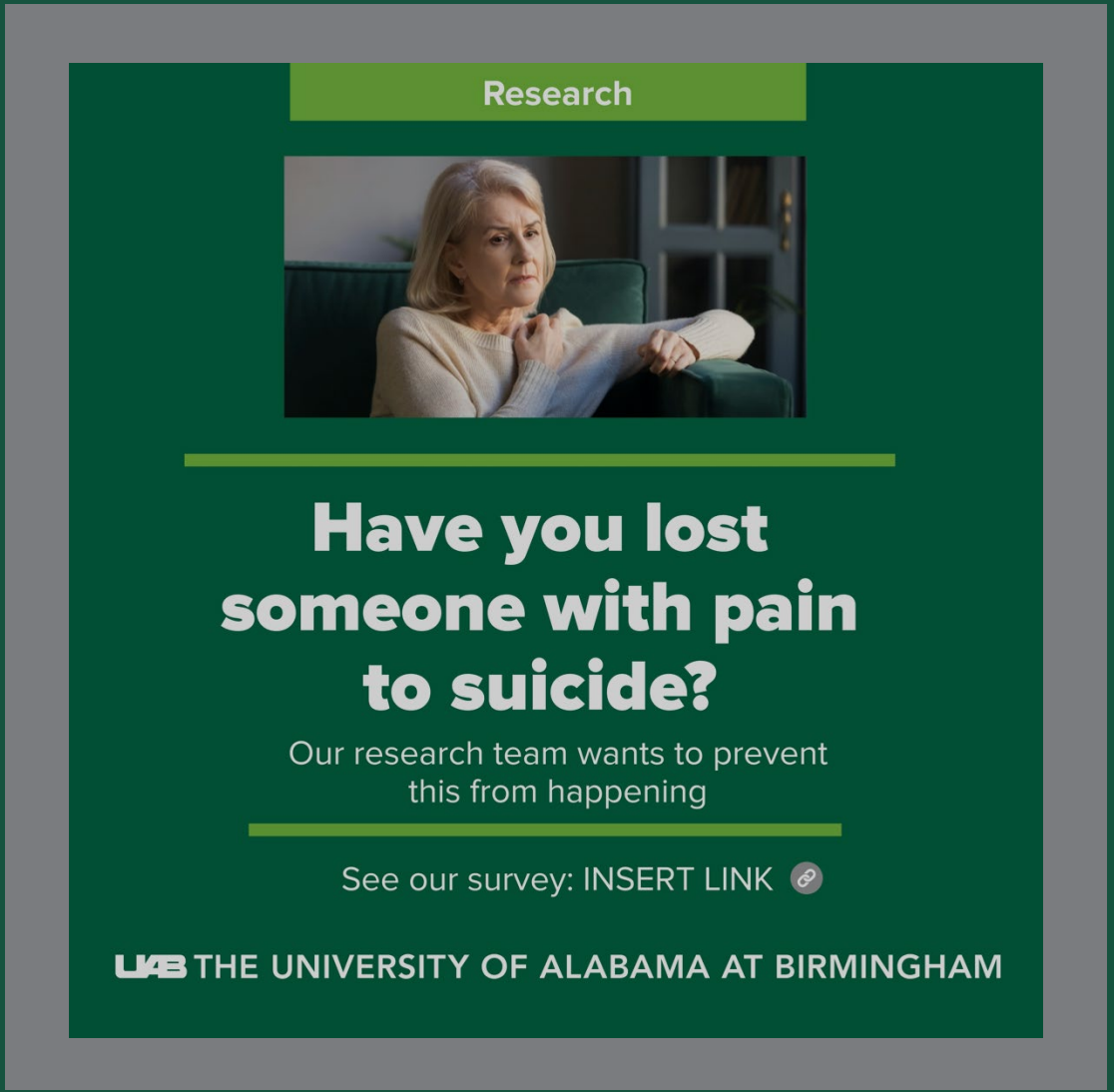
Data of 2019-20

- 6 observational papers with overdose, suicide, illicit drug use or hospitalization outcomes after stoppage (2019-20)[1-6]
- Including 5x ↑ suicide with d/c >90 days[5]
- None "prove" cause and effect
- 81% of doctors "reluctant" to care for a patient on long-term opioids (Quest)[7]
- 41% not willing to provide care for such patients [8]

(1) **Glanz**, 2019 10.1001/jamanetworkopen.2019.2613 (2) **Mark**, 2019 doi: 10.1016/j.jsat.2019.05.001 (3)**James**, JGIM, 2019 (4) **Perez**, 10.1007/s11606-019-05301-2., 2019. (5) **Oliva**, 2020. 10.1136/bmj.m2836. (6) **Coffin**, PloS One, 2020. doi:10.1371/journal.pone.0232538 (7) **Quest** Diagnostics survey, 2019. (8) **Lagisetty**, JAMA NO. 2019. doi:10.1001/jamanetworkopen.2019.6928.

Clinical Questions we Must Study

- Does "taper" confer safety?
- Better we should ask:
- What distinguishes situations with good outcomes from bad ones?
  - Patient factors?
  - Medical factors?
  - Social context?
  - Speed of taper?
  - **Consent** of the patient?
- Why the suicides?



Consolidated Framework for Implementation Research (CFIR)

CFIR components	**CFIR examples we can study:**
Characteristics of individuals	Prescribers' competence, motivation, training
The intervention	For which patients is the change promoted? Is individualization allowed?
Inner setting	Learning climate, psychological safety
Process	Actions taken by the organization
Outer Setting	External metrics, policies, payment and regulatory policies, and public declarations

"Pill dynamic" studies fall short here

Damschroder. Impl Sci. 2009 https://doi.org/10.1186/1748-5908-4-50

Better metrics we should use to study de-implementation (a few examples)

Systems level metrics

Mortality after dose change

Hospitalization after change

Patient level metrics

Appropriateness of dose based on functional outcome documented

Underestimated or Neglected

Number of **patients leaving provider or system** (denominator loss)

Patient perception that care processes are **consensual**

Kertesz, McCullough, Darnall & Varley. *Promoting patient-centeredness in opioid deprescribing: a future for implementation science and policy scholarship* (under revision)

Opioid taper/stoppage is a de-implementation research opportunity (& imperative)

- Clinical research: let's ask what **differentiates** helpful from harmful forms of taper & stoppage?
- Health systems research: let's ask **how** interventions are carried out, who does what, **how** are **missteps** identified, and what role are **patients** allowed to play in their care?
- **Metrics** for studying this problem **now must move beyond pill dynamic studies** to indicators of system change and effects on patients and families
- We have the right questions, and the tools, and the patients who wish to help us do this work. Let's do it.

Thank-you

Questions?

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Follow me @StefanKertesz

thebmj

Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation

Elizabeth M Oliva,[1,2] Thomas Bowe[1,2] Ajay Manhapra,[3,4,5,6] Stefan Kertesz,[7,8] Jennifer M Hah,[9] Patricia Henderson,[1] Amy Robinson,[10] Meenah Paik,[1] Friedhelm Sandbrink[11,12,13] Adam J Gordon,[14,15,16] Jodie A Trafton[1,2,17]

- Veterans who received any opioid analgesic FY13
- Outcomes: death from Overdose OR suicide → end of FY14 (2887 deaths)
- Independent variable: discontinuation or not, interacted with time of receipt before stoppage in Cox non-proportional hazard model

Deaths from suicide ↑5-fold after 91-400 days, ↑8-fold if >400 days receipt

Deaths from overdose similarly elevated

Governmental

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

Framing Voices

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

POLICY ACTORS

Guidances & Metrics

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

Providers & Payors

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