“Opioid deprescribing as a (de-)Implementation Science Challenge
NIH Helping to End Addiction Long-term (HEAL)
June 1, 2020

Stefan G. Kertesz, MD, MSc, FASAM
Professor of Medicine, University of Alabama at Birmingham
Physician, Birmingham Veterans Affairs medical center
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

*This is a fraught moment. A public health concern is involved.*
My thesis

- ~10 million patients on long-term opioids for pain¹
- 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)

The context

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

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

“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

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 3x higher in 2015 than 1999

**Major agency declares a failure to attain goals**

Proportion receiving >90 MME indicates poor performance

**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

Long-term recipients are the de facto central target

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
- Our focus: ~10 million currently on opioids
- All emphasis from payers and metrics is on reduction for them and preventing more of them

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 days⁵
  - 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

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**
- Characteristics of individuals
- The intervention
- Inner setting
- Process
- Outer Setting

**CFIR examples we can study:**
- Prescribers’ competence, motivation, training
- For which patients is the change promoted? Is individualization allowed?
- Learning climate, psychological safety
- Actions taken by the organization
- External metrics, policies, payment and regulatory policies, and public declarations

“Pill dynamic” studies fall short here

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?
skertesz@uabmc.edu

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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
POLICY ACTORS

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

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