Patient-Centered Pain and Opioid Reduction

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Psychiatry and Behavioral Sciences (by courtesy)

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Stanford PCORI Project on Opioid and Pain Reduction (EMPOWER study)
## Beth Darnall, PhD

### Disclosures

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Company(ies)</th>
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<td>Speakers Bureau</td>
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<td>Advisory Committee</td>
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<td>Honorarium</td>
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<td>Royalties</td>
<td>4 books (2 for patients, 2 for healthcare clinicians)</td>
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<td>Ownership Interests</td>
<td>appliedVR</td>
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3.4 % of the U.S. population

11.1 Million

Mojtabai R 2017
What’s at stake?
Growing Outcry Against Iagtrogenic Risks and Harms for Opioid Reduction

- **Nov 2018**: International Stakeholder Letter publishes
  - Darnall BD, Juurlink D, Kerns R, et al.
  - Reuters Wire service
  - 44 news outlets worldwide

- **Dec 2018**: Human Rights Watch
  - Declares the issue a “human rights violation”
  - Laura Mills

- **April 2019**: HP3 Letter
  - Kertesz, Satel, et al.
  - 300+ signatories
  - 3 former U.S. Drug Czars
  - AMA signs support

- **April 2019**: FDA
  - Clarifies labeling and cautions against abrupt discontinuation

- **April 2019**: CDC
  - Dowell, et al.
  - Clarification of opioid prescribing guidelines publish in *NEJM*.
Addressing the dual crises of pain and opioids — a case for patient-centeredness

BY BETH DARNALL, OPINION CONTRIBUTOR — 10/31/18 06:00 PM EDT
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL
Darnall BD. *Pain Med*. 2019

**Applause for the CDC opioid guideline authors**

BY BETH DARNALL, OPINION CONTRIBUTOR — 04/26/19 01:30 PM EDT
THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

**EMPOWER**
EFFECTIVE MANAGEMENT OF PAIN AND OPIOID-FREE WAYS TO ENHANCE RELIEF
Tapering methods matter greatly

• Patient-centered methods enhance patient engagement, safety and outcomes
• Learning health systems can provide point of care supports to characterize, screen, monitor, and provide safety measures in the context of opioid reduction
• Iatrogenic harms from opioid tapering practices must be appreciated, mitigated, and better studied.
• Patient choice and supports are vitally important for successful opioid reduction. Voluntary opioid reduction
Comparative Effectiveness of Pain Cognitive Behavioral Therapy and Chronic Pain Self-Management Within the Context of Voluntary Opioid Reduction

Darnall BD (PI)

EMPOWER Study

Funded by the Patient-Centered Outcomes Research Institute®
Tapering the wrong way

Aggressive Taper

Forced Taper

• Withdrawal Symptoms
• Discomfort
• Distress
• Failed tapers
• False belief that outpatient tapering is impossible
• Remaining on high doses
• Overdose (in SUD)
• Suicidal ideation
• Suicide
Tapering Opioids

Patients’ number one concern/fear?

Not Interested!
Opioid Cessation and Multidimensional Outcomes After Interdisciplinary Chronic Pain Treatment

Jennifer L. Murphy, PhD,* Michael E. Clark, PhD,*† and Evangelia Banou, PhD*

Clin J Pain • Volume 29, Number 2, February 2013

<table>
<thead>
<tr>
<th>Outcome Variables</th>
<th>OP (n = 221)</th>
<th>NOP (n = 379)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Pain intensity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admission</td>
<td>7.01 (1.77)</td>
<td>6.91 (1.58)</td>
</tr>
<tr>
<td>Discharge</td>
<td>6.46 (1.74)</td>
<td>6.14 (1.79)</td>
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Community-Based Solutions are Needed

- Low-cost
- Low-risk
- Scalable
- Effectively reduce health risks
- Provide education and support
- Structured
- Address anxiety of patients and prescribers alike
- Promote patient trust and a good doctor-patient bond
- Enhance patient willingness to try a gentle opioid taper
Research Letter
February 19, 2018

Patient-Centered Prescription Opioid Tapering in Community Outpatients With Chronic Pain

Beth D. Darnall, PhD1; Maica S. Ziedni, PhD1; Richard L. Stieg, MD, MPH2; et al

The risks associated with prescription opioids are well described.1,2 Although reducing opioid use is a national priority, existing opioid tapering models use costly interdisciplinary teams that are largely inaccessible to patients and their physicians.3,4 Patients and physicians need solutions to successfully reduce long-term prescription opioid dosages in settings without behavioral services. We conducted a study of voluntary, patient-centered opioid tapering in outpatients with chronic pain without behavioral treatment.
Opioid Cessation vs. Opioid Reduction
We Optimized Patient Choice and Control in Their Taper

- Participation was VOLUNTARY
- Patients could control the pace of their taper
- Patients could pause their taper
- Patients were free to drop out of the study at any time
- The taper goal was not zero unless the patient chose that goal
- The taper was NOT to a pre-defined opioid dose
- Patients partnered with their doctor to achieve their lowest comfortable dose over 4 months
- The taper was NOT unidirectional

Study Variables

- Demographics (Gender, Age)
- Pain Treatment History (Pain Dx, Duration of Opioid Use)
- Opioid Dose (MEED)
- Average Pain Intensity (0-10)
- Pain Catastrophizing Scale
- PROMIS Measures
- Marijuana use (Y/N)

16 Weeks
Sample Characteristics (N=51)

- 55% female
- 52 years of age (range = 25 – 72)
- 6 years on opioids (range = 1 – 38)
- Moderate pain intensity
- Marijuana: 37% (18)
- Opioid MEDD = 288 (60, 1005)

Darnall BD, Ziadni MS, Mackey IG, Kao MC, Flood P (FEB 2018; JAMA Int Med)
<table>
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<tr>
<th>Variable</th>
<th>Baseline</th>
<th>16 weeks</th>
<th>P-val</th>
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</thead>
<tbody>
<tr>
<td><strong>Opioid Dose (MEDD)</strong></td>
<td>288 (153, 587)</td>
<td>150 (54, 248)</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Pain Intensity (NRS)</strong></td>
<td>5.0 (3.0, 7.0)</td>
<td>4.5 (3.0, 7.0)</td>
<td>0.29</td>
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<tr>
<td><strong>PCS (catastrophizing)</strong></td>
<td>22 (10, 30)</td>
<td>15 (7, 23)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Fatigue</strong></td>
<td>61 (54, 65)</td>
<td>59 (51, 65)</td>
<td>0.64</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td>60 (53, 64)</td>
<td>54 (46, 62)</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td>56 (49, 64)</td>
<td>55 (48, 61)</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>Sleep Disturbance</strong></td>
<td>59 (54, 70)</td>
<td>56 (50, 64)</td>
<td>0.13</td>
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<td><strong>Pain Interference</strong></td>
<td>63 (58, 67)</td>
<td>63 (57, 67)</td>
<td>0.44</td>
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<td><strong>Pain Behavior</strong></td>
<td>60 (57, 63)</td>
<td>59 (56, 64)</td>
<td>0.47</td>
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<tr>
<td><strong>Physical Function</strong></td>
<td>39 (34, 41)</td>
<td>39 (34, 43)</td>
<td>0.78</td>
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*Kruskal-Wallis rank sum test*
Initial Opioid Dose

Absolute Change

Increase
Decrease
Change in Pain Score (NRS)

Percent Change

Increase

Decrease

-100 -50 0 50 100

-4 -3 -2 -1 0 1 2
The Interagency Pain Research Coordinating Committee

National Pain Strategy
A Comprehensive Population Health Level Strategy for Pain

PREScribe RESPONSIBLY.
REDUCE OVERDOSE.

www.cdc.gov GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN
Chronic Pain
Self-Management Program

Two certified trained peer leaders

Darnall BD et al. (protocol manuscript; accepted, *Pain Med*)
1365 patients taking long-term opioids for chronic pain

- Stanford Pain Management Center (CA)
- Stanford Primary Care (CA)
- Intermountain Health (Salt Lake City)
- Veterans Affairs (Phoenix)
- MedNOW Clinics (Denver, CO)
Eligibility
• ≥ 10 MEDD daily for 3 months
• Pain for 6 months

Exclusions:
• Active suicidality
• Unable to participate in behavioral groups
• Moderate to severe Opioid Use Disorder is exclusionary

Screening: 3 items from the TAPS + DSM-V OUD
We must create a caring and safe system that makes patients want to join and remain in EMPOWER
• Easy data entry
• Point of care reporting
• Over 30,000 patients and 100,000 longitudinal data assessments
• NIH PROMIS CAT for comparative metrics and computer adaptive testing to reduce patient burden
• Insights from real-world patients
• Open-source (free) licensing with minimal restrictions
• Comprehensive assessment of:
  • Physical, psychological and social functioning and health
Assessments & Monitoring

Baseline, 6- and 12-month: comprehensive battery
- Psychosocial factors (PROMIS)
- Opioids
- Substance use
- Degree of choice
- Readiness to taper
- Taper beliefs
- Satisfaction with clinician relationship
- Comments

WEEKLY surveys for withdrawal symptoms, mood, comments
MONTHLY surveys for mood, suicidality, opioid dose, satisfaction, comments
Close Monitoring of Patient Response to Opioid Reduction

**WEEKLY surveys** for withdrawal symptoms, mood, comments

**MONTHLY surveys** for mood, suicidality, opioid dose, satisfaction, comments

- Alerts are sent to prescribers in real time
- Patients receive tailored messages

We track patients over 12 months
Patient Stories
Lessons Learned

• A great need: Much interest in EMPOWER, requests to become a site
• RCTs within a medical trial are extra challenging
• Survey burden has been less of a “burden” than expected
• High degree of physician/clinician engagement required to help patients understand the value of tapering and feel safe in the process
Colleagues and Collaborators

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Learn More

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- #PCORI2019
- EMPOWER Study
Questions?