Improving community-based care for chronic pain: antidote to the opioid epidemic

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**VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN**

Version 1.0

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>QE</th>
<th>Overall Quality</th>
<th>R</th>
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</thead>
<tbody>
<tr>
<td>Opioid therapy is indicated for moderate to severe pain that has failed other therapeutic interventions</td>
<td>III</td>
<td>Poor</td>
<td>I</td>
</tr>
<tr>
<td>Consider the ethical imperative to relieve pain</td>
<td>III</td>
<td>III</td>
<td>I</td>
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</table>

Opinion of respected authorities, case reports, and expert committees

Management of Opioid Therapy for Chronic Pain Working Group, March 2003
<table>
<thead>
<tr>
<th>#</th>
<th>Recommendation</th>
<th>Strength*</th>
<th>Category†</th>
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</table>
| 1 | a) We recommend against initiation of long-term opioid therapy for chronic pain.  
b) We recommend alternatives to opioid therapy such as self-management strategies and other non-pharmacological treatments.  
c) When pharmacologic therapies are used, we recommend non-opioids over opioids.                                                                 | a) Strong against  
b) Strong for  
c) Strong for                                 | Reviewed, New-replaced                           |
"No study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy evaluated long-term (>1 year) outcomes related to pain, function, or quality of life."

**Strategies for Prescribing Analgesics**

**Comparative Effectiveness Trial**

**Objective:** To compare benefits and harms of opioid therapy versus non-opioid medication therapy over 12 months among patients with chronic back or osteoarthritis (OA) pain

- **H1:** Opioids will improve pain-related function & pain intensity more than non-opioids
- **H2:** Opioids will cause more adverse medication-related symptoms and events than non-opioids

ClinicalTrials.gov: NCT01583985
240 Veterans with chronic low back or arthritis pain

Opioid pain medications

Non-opioid medications

12 months

Function
Pain
Side effects

Funded by VA Health Services Research & Development IIR 11-125
Eligibility

• Inclusion criteria: Moderate-severe chronic back pain or hip/knee OA pain despite analgesic use

• Major exclusion criteria
  – Absolute contraindications to opioid therapy
  – Cognitive impairment or psychosis
  – Current long-term opioid therapy
Interventions

• Patients randomized to opioid or non-opioid arm
• All patients received individualized medication management within assigned arm
  – Follow-up visits monthly, then Q1-3 months
  – Treatment to target pain & individual functional goals
  – Telecare collaborative pain management

• TCM intervention components
  – Symptom monitoring: PEG, PHQ-2, GAD-2
  – Medication optimization
• Pain improvement: 52% intervention vs. 27% usual care (NNT 4.1)
Medication arms

- All medications in both arms on VA formulary
- Each arm included 3 medication steps
- Opioid daily dose limited to 100 ME mg/day
  - (Initial plan was 200 ME mg/day)
### Medication arms

<table>
<thead>
<tr>
<th>Table: Medications within arms</th>
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<table>
<thead>
<tr>
<th></th>
<th><strong>Opioid arm</strong></th>
<th><strong>Non-opioid arm</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td>Morphine IR*</td>
<td>Acetaminophen*</td>
</tr>
<tr>
<td></td>
<td>Oxycodone IR</td>
<td>Oral NSAIDs</td>
</tr>
<tr>
<td></td>
<td>Hydrocodone/APAP</td>
<td>Diclofenac topical</td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td>Morphine SR</td>
<td>Nortriptyline, amitriptyline</td>
</tr>
<tr>
<td></td>
<td>Oxycodone SA</td>
<td>Gabapentin</td>
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<tr>
<td></td>
<td></td>
<td>Lidocaine topical</td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td>Fentanyl transdermal (Methadone)</td>
<td>Pregabalin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duloxetine</td>
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<tr>
<td></td>
<td></td>
<td>Tramadol</td>
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</table>

* Preferred initial medication selection
265 Enrolled
240 Randomized
25 Excluded

**Opioid arm**
- 120 Assigned
- 119 Received intervention

**Non-opioid arm**
- 120 Assigned
- 120 Received intervention

**12-month follow-up**
- **Opioid arm**
  - 117 Assessed
  - 1 Dropout, 2 Lost
  - 119 Included in analysis

- **Non-opioid arm**
  - 117 Assessed
  - 1 Dropout, 1 Lost, 1 Unavailable
  - 119 Included in analysis
Response at 12 months: pain-related function and pain intensity

<table>
<thead>
<tr>
<th></th>
<th>Opioid (n=117)</th>
<th>Non-opioid (n=117)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPI interference</td>
<td>69 (59.0%)</td>
<td>71 (60.7%)</td>
<td>0.722</td>
</tr>
<tr>
<td>BPI severity</td>
<td>48 (41.0%)</td>
<td>63 (53.9%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Intervention contacts</td>
<td>Opioid (n=120)</td>
<td>Non-opioid (n=120)</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
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<tr>
<td>Clinic visits, number</td>
<td>2.8 ± 2.0</td>
<td>2.8 ± 2.1</td>
<td></td>
</tr>
<tr>
<td>Phone visits, number</td>
<td>6.1 ± 2.9</td>
<td>6.2 ± 2.6</td>
<td></td>
</tr>
<tr>
<td>Visit duration, minutes</td>
<td>230 ± 95.5</td>
<td>216 ± 82.5</td>
<td></td>
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</table>
Summary

- Opioid therapy was not superior to non-opioid medication therapy over 12 months
  - Pain-related function: no difference
  - Pain intensity: small significant difference favoring non-opioids
- Opioid therapy caused significantly more medication-related adverse symptoms
Implications of study findings

- Results support CDC guideline recommendation that non-opioid medications are preferred for chronic pain
- Relatively high response rates in both arms, consistent with prior trial of similar TCM intervention
What next?

De-implement inappropriate opioid therapy

Implement effective pain therapies
Prompted by White House summit on prescription opioid crisis
Focus on alternatives to opioid therapy
Objectives

• To synthesize existing evidence and gaps related to non-pharmacological approaches for chronic musculoskeletal pain management
  – Psychological/behavioral therapies
  – Exercise/movement therapies
  – Manual therapies
  – Models for care delivery
• To identify approaches ready for implementation
• To identify a research agenda
Approaches ready for implementation (sufficient evidence)

- Acupuncture
- Cognitive Behavioral Therapy
- Acceptance & Commitment Therapy
- Manual therapies
  - Manipulation
  - Massage
- Mindfulness Based Stress Reduction
- Exercise/movement therapies
  - Aerobic exercise
  - Coordination/stabilization exercise
  - Resistance exercise
- Behavioral/Psychological therapies
  - Yoga
  - Tai chi
Research agenda (evidence gaps)

• For most therapies, need further study of…
  – Delivery approaches
  – Dose (e.g., frequency, intensity, duration)
  – Strategies for improving adherence
  – Strategies for maintaining benefits
  – Effects of combining and sequencing therapies
Models for pain care delivery

- Unable to identify published systematic reviews
- Requested an evidence brief from the VA Evidence-Synthesis Program to include studies of…
  - Models using system-based mechanisms to increase uptake and organization of multimodal pain care
  - Adults with chronic musculoskeletal pain
  - Interventions integrated with primary care, excluding those conducted entirely within specialty settings
Models for pain care delivery

- 11 articles (10 studies) included
- Most RCTs of fair-good quality (3 poor)
- Most had 12 month follow-up (range 6-18)
- Most used usual care control
- Baseline mean pain on 11-point scale: 5.1-7.7
- 9 diverse models

Peterson K, et al. Evidence Brief: Effectiveness of Models Used to Deliver Multimodal Care for Chronic Musculoskeletal Pain. VA ESP Project #09-199; 2017
Models for pain care delivery

• Best evidence for 5 models
  – 4 good-quality VA trials combined decision support with case management: ESCAPE, SEACAP, SCAMP, and SCOPE
  – 1 fair-quality British trial combined risk stratification with risk-matched treatment pathways: STarT Back
    – Clinically relevant improvement in pain intensity & pain-related function over 9-12 months (NNT range 4.1-12.70)

• Consider implementation of models across multiple VA facilities, with further evidence development

Peterson K, et al. Evidence Brief: Effectiveness of Models Used to Deliver Multimodal Care for Chronic Musculoskeletal Pain. VA ESP Project #09-199; 2017
Implementation challenges
Implementation challenges

Access to medications

Access to evidence-based non-pharmacological therapies
Thank you!

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