NOHARM

Non-pharmacological Options in post-operative Hospital-based And Rehabilitation pain Management pragmatic trial -

Andrea Cheville, MD, MSCE & Jon Tilburt, MD
Non-pharm pain care (NPPC) is robustly validated but under-utilized

• Guidelines uniformly endorse NPPC for post-operative pain
• Rehabilitate and integrative approaches are safe, effective, and reduce non-pain symptoms
• Rehabilitate and integrative approaches are not systemically integrated into perioperative care
Challenges:
- Perioperative care encompasses diverse:
  - Clinicians
  - Settings
  - Workflows
  - Diseases and conditions
- Series of “saturated” clinical touch points
  - None in isolation suffice to advance NPPC use
- Patients have varied and evolving NPPC preferences
The EHR offers a common point of convergence

**Prompt clinicians via CDS to:**
- Introduce NOHARM NPPC
- Normalize use
- Support options
- Direct patients to NOHARM resources

**Nexus for multi-stakeholder bi-directional information exchange**

**Direct patients via portal-based messages to:**
- Learn about NPPC and opioid harms/benefits
- Select preference-concordant NPPC options
- Troubleshoot and advance NPPC use
- Access resources
NOHARM Intervention:


2. Suite of self-management educational materials and zoom support calls

3. Clinician-directed Epic-based Clinical Decision Support (CDS)
Non-Pharm Pain Care (NPPC): Validated for Post-Op Pain Management

<table>
<thead>
<tr>
<th>Movement</th>
<th>Physical</th>
<th>Relaxation</th>
</tr>
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<tbody>
<tr>
<td>Walking</td>
<td>Acupressure</td>
<td>Meditation</td>
</tr>
<tr>
<td>Yoga</td>
<td>Massage</td>
<td>Breathing</td>
</tr>
<tr>
<td>Tai Chi</td>
<td>Cold or Heat</td>
<td>Music</td>
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<td></td>
<td>TENS</td>
<td>Guided Imagery</td>
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<tr>
<td></td>
<td></td>
<td>Muscle Relaxation</td>
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<tr>
<td></td>
<td></td>
<td>Aromatherapy</td>
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</tbody>
</table>
**NOHARM Population-level, Stepped Wedge, Cluster-randomized Implementation Strategy**

<table>
<thead>
<tr>
<th>Tranche 1</th>
<th>Tranche 2</th>
<th>Tranche 3</th>
<th>Tranche 4</th>
<th>Tranche 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong>&lt;br&gt;Rochester&lt;br&gt;Cardiac, C-Section&lt;br&gt;<strong>Florida</strong>&lt;br&gt;Ortho&lt;br&gt;<strong>Eau Claire</strong>&lt;br&gt;Ortho, Colorectal, Gyn, C-Section&lt;br&gt;<strong>La Crosse</strong>&lt;br&gt;Gyn, C-Section</td>
<td><strong>Step 1</strong>&lt;br&gt;Rochester&lt;br&gt;Ortho, Gyn, Lung&lt;br&gt;<strong>Arizona</strong>&lt;br&gt;Lung, Cardia&lt;br&gt;<strong>Mankato</strong>&lt;br&gt;Colorectal</td>
<td><strong>Step 2</strong>&lt;br&gt;Rochester&lt;br&gt;Colorectal&lt;br&gt;<strong>Florida</strong>&lt;br&gt;Transplant&lt;br&gt;<strong>Arizona</strong>&lt;br&gt;Colorectal, Gyn, Transplant</td>
<td><strong>Step 2</strong>&lt;br&gt;Florida&lt;br&gt;Colorectal, Gyn, Lung, Cardia&lt;br&gt;<strong>Eau Claire</strong>&lt;br&gt;Lung, Cardiac&lt;br&gt;<strong>Mankato</strong>&lt;br&gt;C-Section</td>
<td><strong>Step 2</strong>&lt;br&gt;Rochester&lt;br&gt;Transplant&lt;br&gt;<strong>Arizona</strong>&lt;br&gt;Ortho&lt;br&gt;<strong>Mankato</strong>&lt;br&gt;Ortho&lt;br&gt;<strong>La Crosse</strong>&lt;br&gt;Ortho, Colorectal</td>
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<tr>
<td><strong>Control Condition</strong>&lt;br&gt;Data Collection&lt;br&gt;10/16/2020</td>
<td><strong>Step 1</strong>&lt;br&gt;Go Live&lt;br&gt;3/1/2021</td>
<td><strong>Step 2</strong>&lt;br&gt;Go Live&lt;br&gt;10/1/2021</td>
<td><strong>Step 3</strong>&lt;br&gt;Go Live&lt;br&gt;5/1/2022</td>
<td><strong>Step 4</strong>&lt;br&gt;Go Live&lt;br&gt;12/1/2022</td>
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<td><strong>Step 1</strong>&lt;br&gt;Go Live&lt;br&gt;3/1/2021</td>
<td><strong>Step 2</strong>&lt;br&gt;Go Live&lt;br&gt;5/1/2022</td>
<td><strong>Step 3</strong>&lt;br&gt;Go Live&lt;br&gt;12/1/2022</td>
<td><strong>Step 4</strong>&lt;br&gt;Go Live&lt;br&gt;7/1/2023</td>
<td><strong>Step 5</strong>&lt;br&gt;Go Live&lt;br&gt;7/1/2023</td>
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Outcomes

• Primary
  • Pain interference
  • Physical function

• Secondary
  • Opioid consumption
  • Anxiety
  • Healthcare utilization
Physical Point-of-Care Delivery Sites
EHR Build

- Registry & CG Assignment
- Surgery Order Placed
- NPPC Selections Entered
- Prompt NPCC Selection if Missing & Encourage Use
- Pain >1/10; RN Initiates Selection-Matched Intervention
- RNs Prompted to Query re: Use NPPC Each Shift
- PTs & OTs Integrate NPPC in Treatment
- NPPC Info on D/C Summary
- Opioid Refill Request; Portal Message to Prompt NPPC
- Off Registry at 3 Months

Pain >1/10; RN Initiates Selection-Matched Intervention
RNs Prompted to Query re: Use NPPC Each Shift
PTs & OTs Integrate NPPC in Treatment
NPPC Info on D/C Summary
Opioid Refill Request; Portal Message to Prompt NPPC
Off Registry at 3 Months
Prompt NPPC selection if missing & encourage use

NPPC selections entered

Registry & CG assignment

Surgery order placed

NPPC info on D/C summary

Pain >1/10, RN initiates selection-matched intervention

RNs prompted to query re. use NPPC each shift

PTs & OTs integrate NPPC in treatment

NPPC info on D/C summary

Portal message to prompt NPPC

Yes

Opioid refill request

No

Off registry at 3 mo.
### Patient enrollment and flow as of 3/25/22

#### Completed study

<table>
<thead>
<tr>
<th>Location</th>
<th>Rochester</th>
<th>Florida</th>
<th>Arizona</th>
<th>Mankato</th>
<th>La Crosse</th>
<th>Eau Claire</th>
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<tbody>
<tr>
<td>Completed</td>
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<td>2,818</td>
<td>2,877</td>
<td>511</td>
<td>439</td>
<td>810</td>
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<td><strong>Total</strong></td>
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#### Study Subjects Still Active

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<tr>
<th>Location</th>
<th>Rochester</th>
<th>Florida</th>
<th>Arizona</th>
<th>Mankato</th>
<th>La Crosse</th>
<th>Eau Claire</th>
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<tr>
<td>4,024</td>
<td>1,355</td>
<td>1,282</td>
<td>418</td>
<td>362</td>
<td>555</td>
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<td><strong>Total</strong></td>
<td><strong>7,996</strong></td>
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#### Lost to follow up (Off study 3 mo. – no follow up data)

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<tr>
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<th>Rochester</th>
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<th>Mankato</th>
<th>La Crosse</th>
<th>Eau Claire</th>
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<tbody>
<tr>
<td>3,293</td>
<td>893</td>
<td>985</td>
<td>574</td>
<td>362</td>
<td>760</td>
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<tr>
<td><strong>Total</strong></td>
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#### Order place for NOHARM qualifying surgery

<table>
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<tr>
<th>Location</th>
<th>Rochester</th>
<th>Florida</th>
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<th>Mankato</th>
<th>La Crosse</th>
<th>Eau Claire</th>
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<tbody>
<tr>
<td>17,535</td>
<td>5,860</td>
<td>5,907</td>
<td>1,682</td>
<td>1,303</td>
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<td><strong>Total</strong></td>
<td><strong>34,643</strong></td>
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Thank you for your kind attention!

We wish to extend heartfelt thanks to our partners within the HEAL Initiative, NIA, NICHD, and NIH Clinical Trials Collaboratory, as well as our patient participants.