NOHARM

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

a HEAL UG3 Demonstration Project

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Collaboratory Kick-Off Meeting
November 19-20, 2019
Bethesda, MD
What if we could…?

• Reduce perioperative opioid prescribing
• Honor patient preferences for non-pharm pain care
• Steer at-risk patients away from opioids
• … while preserving acceptable post-op outcomes

AND

• Leverage EHR platforms to integrate w/in workflows
• … in major health systems
NOHARM’s Overall Goal: Nudge Practice

- Change the post-op pain care default paradigm from
  - Opioids + maybe non-pharm options
  - To safe non-pharm + maybe opioids
  - For post-acute care
  - Attentive to
    - high risk groups
    - Downsides of over-restriction
Background & Significance

- Post-op opioid prescribing contributes to the opioid epidemic
- Opioids are necessary but not sufficient in post-surgical care
- Guidelines recommend non-pharm pain care (NPPC) 1st
- No studies showing how to make NPPC more viable post-op
- EHRs can help elicit and advance patients’ NPPC preferences
- Our gamble: partner w/practices + engage patients w/EHR = reduced harm within a committed national surgical practice
- Goal: test bundled pragmatic intervention of conversation guide (CG) and clinical decision support (CDS) w/in EHRs
- to improve outcomes and reduce post-op opioid consumption
Aims

1. Confirm feasibility of each NOHARM component
2. Test impact of a bundled conversation guide (CG) + clinical decision support (CDS) on post-op opioid use (OMEs), pain, and fxn.
3. Evaluate adoption & implementation in high risk patients
Leveraging the EHR to advance a consistent narrative across perioperative touchpoints

1. Access conversation guide via portal:
   Develop individualized NPPC plan

2. Presurgical check in:
   Confirm NPPC plan, revise per preference, view video PRN

3. In-hospital therapy:
   Initiate NPPC plan, emphasize self-management, adapt PRN

4. Hospital discharge:
   Review NPPC plan, provide supplies, education, & local resources
   Refer to NPPC resources, complete PRO screening

5. Access conversation guide via portal:
   Potential adverse event - increased pain:
   Alert clinical team, prompt referral

6. Postoperative clinic follow up:
   Query use of NPPC, trouble shoot, opioid taper PRN

Potential response:
Medication Therapy Management visit with pharmacist

Perioperative Care Pathway
**Population**

- **Surgical Practices:** Ortho, GYN, Colorectal
- **Mayo Clinic Sites:** MN, AZ, FL, MCHS

<table>
<thead>
<tr>
<th>Site</th>
<th>Overall</th>
<th>Amputation</th>
<th>Colorectal</th>
<th>Gynecology</th>
<th>Arthroplasty</th>
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<tr>
<td>Arizona</td>
<td>5823 (15.0%)</td>
<td>58 (10.3%)</td>
<td>593 (13.3%)</td>
<td>3326 (17.0%)</td>
<td>1846 (13.0%)</td>
</tr>
<tr>
<td>Florida</td>
<td>4832 (12.5%)</td>
<td>73 (13.0%)</td>
<td>577 (12.9%)</td>
<td>2201 (11.2%)</td>
<td>1981 (14.0%)</td>
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<tr>
<td>MCHS</td>
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<td>718 (16.1%)</td>
<td>4677 (23.9%)</td>
<td>4446 (31.3%)</td>
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<td>Rochester</td>
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<td>303 (53.9%)</td>
<td>2585 (57.8%)</td>
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<td>5916 (41.7%)</td>
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Study design:
Stepped wedge, cluster-randomized pragmatic clinical trial
# Outcomes

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<th></th>
<th>Mode</th>
<th>Pre-op</th>
<th>In-hosp.</th>
<th>Discharge</th>
<th>Rehab Facil.</th>
<th>Outpt. clinic</th>
<th>0-3 mo.</th>
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<tr>
<td>OMEs</td>
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<td></td>
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<td>✓</td>
<td>✓</td>
<td>✓*</td>
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<td>Self-report</td>
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<tr>
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<td>✓</td>
<td>✓</td>
<td>✓*</td>
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<tr>
<td>Modalities</td>
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<td>✓</td>
<td>✓</td>
<td>✓*</td>
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Year 1 (UG3)

• Refine & Pilot Conversation Guide
• Optimize CDS usability
• Develop engagement and training materials for clinical stakeholders
• Pilot all data collection elements
• Engage IRB
• Confirm feasibility at all sites
Patients: NPPC preference elicitation and EHR entry
Physicians & APPs: Apprise, prompt, direct
Allied health professionals: Initiate, titrate, reassess
Cultivating Collaborative IRB Relationship

• Mayo IRB
  • R. Scott Wright, chair
    • Committed to innovating
    • Co-learning with national “collaborative”
  • Phased approval process
    • Conversation guide development
    • Piloting data collection, pilot data r.e. authorization, interventions (CG&CDs),
    • Mature trial @ all sites
IRB Relationship: Discussing Consent Options/Alternatives

• Complete waiver
• Broadcast information
• Integrated consent
• Simple opt-out
• Simple opt-in (oral/written)
• Short form
• Electronic
• Standard Consent
Date Sharing UG3

• What is your current data sharing plan and do you foresee any obstacles?
• What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?
• What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?
Current Data Sharing Plan & Obstacles

“de-identified data collected for NOHARM will be made available and encrypted during transfer”

• Obstacles? all within Mayo Clinic
IRB Requirements

- Still in discussions, not settled
- Consent model not decided
- MN statute requiring research authorization

“Data collected from patients who have not given permission for use of their EHR data for research will not be utilized in the NOHARM trial analyses, reported on, or transferred to the PRISM Centers or outside institutions”
Data We’re Planning to Share

• Not decided (candidates below)
• EHR & self-report (not PDMP)
• PROs
• OMEs
• Surgical Outcomes monitoring program
• ??? Patient characteristics
• Site & practice characteristics
## Barriers Scorecard

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>x</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>x</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>x</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>x</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>x</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>x</td>
</tr>
</tbody>
</table>

*Your best guess!  
1 = little difficulty  
5 = extreme difficulty
Thanks!

Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)
Thank You

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