NOHARM

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

a HEAL and PRISM UG3/UH3 Demonstration Project

Andrea Cheville, MD, MSCE & Jon Tilburt, MD
NIH Pragmatic Trials Collaboratory SC Meeting
May 16-17, 2023
Bethesda, MD
Pragmatic trial to promote non-pharmacological pain care after surgery touching patients across peri-operative continuum
# Stepped-wedge cluster-randomized trial

<table>
<thead>
<tr>
<th>Control condition</th>
<th>Data Collection 10/16/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Go live 3/1/2021</td>
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<tr>
<td>Step 2</td>
<td>Go live 10/1/2021</td>
</tr>
<tr>
<td>Step 3</td>
<td>Go live 5/1/2022</td>
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<tr>
<td>Step 4</td>
<td>Go live 12/1/2022</td>
</tr>
<tr>
<td>Step 5</td>
<td>Go live 7/1/2023</td>
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</tbody>
</table>

### Tranche 1
- Rochester
- Cardiac, C-Section
- Florida
- Ortho
- Eau Claire
- Ortho, Colorectal, Gyn, C-section
- LaCrosse
- Gyn, C-Section

### Tranche 2
- Rochester
- Ortho, Gyn, Lung
- Arizona
- Lung, Cardiac
- Mankato
- Colorectal

### Tranche 3
- Rochester
- Colorectal
- Florida
- Transplant
- Arizona
- Colorectal, Gyn, Transplant

### Tranche 4
- Florida
- Colorectal, Gyn, Lung, Cardiac
- Eau Claire
- Lung, Cardiac
- Mankato
- C-Section

### Tranche 5
- Rochester
- Transplant
- Arizona
- Ortho
- Mankato
- Ortho
- LaCrosse
- Ortho, Colorectal
Non-Pharmacological Pain Care

**Movement**
- Walking
- Yoga
- Tai Chi

**Relaxation**
- Meditation
- Relaxed Breathing
- Music Listening
- Guided Imagery
- Muscle Relaxation
- Aromatherapy

**Physical**
- Acupressure
- Massage
- Cold or Heat
- TENS
Current Status

1. 63,744/80,000 patients accrued
2. On track for accrual through Jan 31, 2024
3. Outcome measurement closes May 31, 2024
<table>
<thead>
<tr>
<th>Barriers</th>
<th>Level of Difficulty*</th>
</tr>
</thead>
<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
Top challenges

• Unpredictable EHR instability
  • Intervention assignment logic
  • PROM assignment logic
• Consistency of staffing and staff engagement
  • Turnover, cross-coverage, use of locums
• Competing staff demands
• EHR data abstraction and curation
Recent Generalizable Lesson Learned

- Critical importance of:
  - Scheduled, standardized EHR functionality checks
  - Continued engagement & implementation
    - Effective approaches are contextual
    - Chocolate is a powerful catalyst
- Delicate balance between clinician buy-in and annoyance
- “Passive” and “scalable” are relative terms
- Culture, Culture, Culture
Data We’re Planning to Share via ICPSR

- Demographics
- Comorbidities
- Surgical type
- Patient Reported Outcomes (PROMIS, NRS)
  - Primary – pain, physical function
  - Secondary – anxiety, self-efficacy
- Opioid use – self-report, administered, prescriptions
- NPPC Use
Current Data Sharing Plan & Obstacles

• Share select elements of cleaned, curated analytic data set

• Obstacles
  • Optimal SQL query specification
    • Medications
    • Comorbidities
  • Inconsistent EHR data entry patterns across sites
  • Time consuming variable adjudication
  • Analyst effort
Thank You

tilburt.jon@mayo.edu
cheville.andrea@mayo.edu