

MAYOCLINIC ROBERT D. AND PATRICIA E. KERN CENTER FOR THE SCIENCE OF HEALTH CARE DELIVERY



# **NOHARM**

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

a HEAL and PRISM UG3/UH3 Demonstration Project

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# Pragmatic trial to promote non-pharmacological pain care after surgery touching patients across peri-operative continuum



## Stepped-wedge cluster-randomized trial

	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
Control	Data Collection				
condition	10/16/2020				
Step 1	Go live 3/1/2021				
Step 2		Go live 10/1/2021			
Step 3			Go live 5/1/2022		
Step 4				Go live 12/1/2022	
Step 5					Go live 7/1/2023



## 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



## **Barriers Scorecard**

	Level of Difficulty*					
Barriers	1	2	3	4	5	
Enrollment and engagement of patients/subjects	X					
Engagement of clinicians and health systems			X			
Data collection and merging datasets			X			
Regulatory issues (IRBs and consent)		X				
Stability of control intervention			X			
Implementing/delivering intervention across healthcare organizations			X			

<sup>\*</sup>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

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