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**CENTER FOR THE SCIENCE OF  
HEALTH CARE DELIVERY**



# 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  
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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) 1<sup>st</sup>
- 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 advanced a consistent narrative across perioperative touchpoints



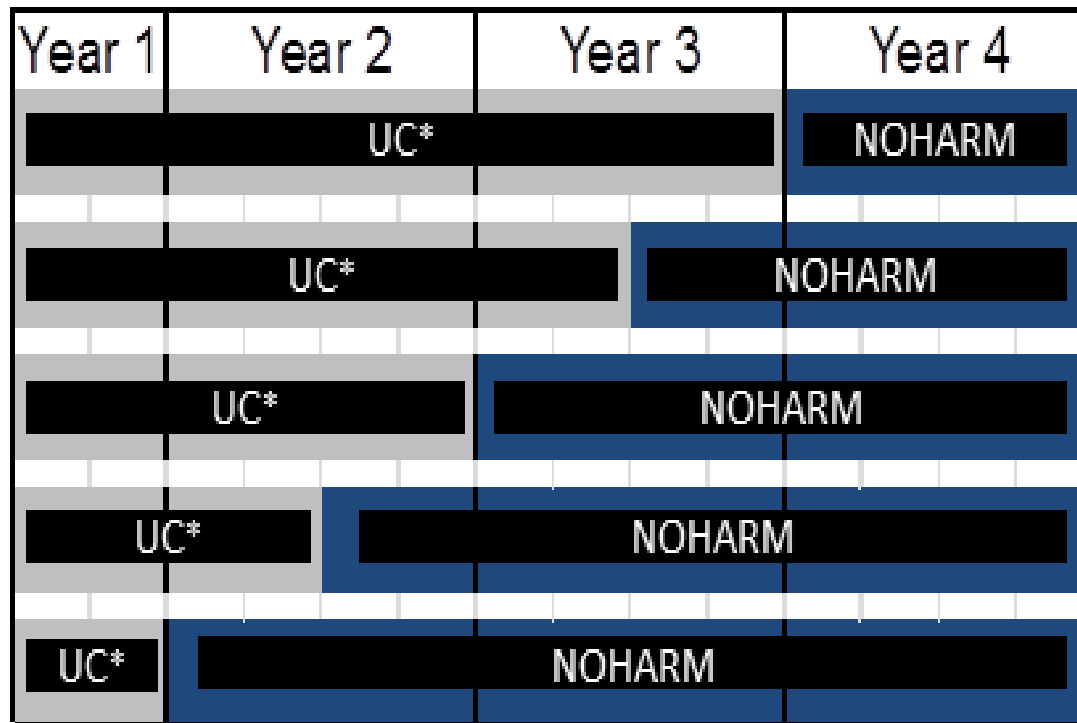
# Population

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



Site	Overall	Amputation	Colorectal	Gynecology	Arthroplasty
Arizona	5823 (15.0%)	58 (10.3%)	593 (13.3%)	3326 (17.0%)	1846 (13.0%)
Florida	4832 (12.5%)	73 (13.0%)	577 (12.9%)	2201 (11.2%)	1981 (14.0%)
MCHS	9969 (25.7%)	128 (22.8%)	718 (16.1%)	4677 (23.9%)	4446 (31.3%)
Rochester	18179 (46.8%)	303 (53.9%)	2585 (57.8%)	9375 (47.9%)	5916 (41.7%)

# Study design: Stepped wedge, cluster-randomized pragmatic clinical trial





# Outcomes

	Mode	Pre-op	In-hosp.	Dis-charge	Rehab Facil.	Outpt. clinic	0-3 mo.	3 mo.
<b>Opioid use</b>								
OMEs	Self-report	✓*				✓	✓	✓*
OMEs	RN logged		✓		✓			
Prescriptions	EHR	✓		✓	✓	✓	✓	
Refill requests	EHR				✓	✓	✓	
<b>Pain</b>								
PROMIS CAT	Self-report	✓*				✓	✓	✓*
NRS	RN logged		✓		✓			
<b>Function</b>								
PROMIS CAT	Self-report	✓*				✓	✓	✓*
6 clicks	PT logged		✓					
<b>Anxiety</b>								
PROMIS CAT	Self-report	✓*				✓	✓	✓*
<b>NPPC use</b>								
Modalities	Self-report	✓*				✓	✓	✓*

## 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

Developing a plan to manage your pain after surgery, is the first step to getting better.

There are many ways to treat pain. Start by watching this short video.

WATCH VIDEO

Ready to start planning?

**For me**  
Take the time to write down what's most important to you.

START

**For my doctor**  
Let your doctors know what can provide the best care for

Education

## My preferences

Please indicate how much you agree with the following statements.

I enjoy massages and being touched in a healing manner.

Not at all Somewhat Mostly Completely

Devices that administer energy to body can relieve pain and improve healing.

Not at all Somewhat Mostly Completely

Being bandaged or wearing a garment that limits my movement does not bother me.

Not at all Somewhat Mostly Completely

I enjoy exercise and movement.

Not at all Somewhat Mostly Completely

Yoga, Tai Chi, and other types of integrative physical activities can help with strength and relaxation

Not at all Somewhat Mostly Completely

I know exactly the kind of music that relaxes me.

Not at all Somewhat Mostly Completely

Trying to calm my mind is frustrating and difficult.

Not at all Somewhat Mostly Completely

I become bored by repetitive exercise.

Not at all Somewhat Mostly Completely

CONTINUE FINISH LATER CANCEL

Thank you for responding. Please advance to view your pain management preference list.

Elicitation

## What is most important to me?

My Options	Watch to Learn More	Preference Scale							My Choices
		Pain Relief	Cost	Side Effects	Risk of Dependency	Resume Regular Activities	Improve Other Symptoms	Easy to Access	
<b>PHYSICAL</b>									
Transcutaneous electrical nerve stimulations	▶	++	\$\$	Skin Irritation	0%	+	No Evidence	++	●
Compression	▶	+	\$	Restriction	0%	+	No Evidence	++	●
<b>PSYCHOLOGICAL</b>									
Mindfulness	▶	None	None	None	0%	No Evidence	++	+++	●
Music	▶	None	None	None	0%	No Evidence	++	+++	●
<b>EXERCISE</b>									
Resistive/aerobic	▶	None	\$	Soreness	0%	No Evidence	+	++	●
Yoga	▶	None	\$	Soreness	0%	No Evidence	+	++	●
<b>TOUCH</b>									
Massage	▶	++	\$	Soreness	0%	No Evidence	No Evidence	++	●
Reiki	▶	++	\$	Soreness	0%	No Evidence	No Evidence	++	●
<b>RX</b>									
Opioid Medications	▶	+++	\$\$\$	Upset Stomach, Kidney Damage	25%	Delayed	No Evidence	+	●
Anti-inflammatory	▶	+++	\$\$	Upset Stomach, Kidney Damage	0%	+	No Evidence	++	●

Selection

# Physicians & APPs: Apprise, prompt, direct

Synopsis

Symptom Profile Obesity Profile Hypertension Profile 6 Months 07/

Days 0/4/2017 10/18/2017 Most Recent Value

All Last 6 Months

⚡ Patient Spotlight  
No data to display.

⚡ Vitals

Temp	C (98.8 °F)	37 °C (98.6 °F)	37 °C (98.6 °F)	10/18/2017
Pulse		88	88	10/18/2017
BP	2	118/62	118/62	10/18/2017
Resp		18	18	10/18/2017
Weight	g		60.8 kg	10/4/2017
Height	m		1.702 m	10/4/2017
BMI (Calculated)			21	10/4/2017

⚡ Anxiety  
No data to display.

⚡ Physical Function  
No data to display.

⚡ Opioid Misuse  
No data to display.

⚡ Opioid consumption  
No data to display.

⚡ Pain Interference

⚡ Nonpharmacological Pain Care

← Pain Score

Apprise

Nonpharmacological Pain Management ^

▼ Referrals for patients requesting opioid refills

- ▶ Massage Referral [Click for more](#)
- ▶ Pharmacist Medical Review Referral [Click for more](#)
- ▶ Pain Clinic Referral [Click for more](#)
- ▶ Psychology Referral [Click for more](#)
- ▶ Physical Therapy Referral [Click for more](#)

Prompt

**The patient may require an opioid refill but other options should be explored.**

⚠

[Link to NPPC preference list](#) [Link](#)

[Link to Synopsis Pain Summary view](#) [Link](#)

Open SmartSet	Do Not Open	Nonpharmacological Pain Management <a href="#">Preview</a>
Add Problem	Do Not Add	Anxiety <a href="#">Edit details</a> (Share with patient)
Add Problem	Do Not Add	Pain <a href="#">Edit details</a> (Share with patient)
Add Problem	Do Not Add	Opioid use disorder, mild, abuse <a href="#">Edit details</a> (Share with patient)

Acknowledge Reason

Declines  NPPC ineffective  Low abuse risk  Function improving

[Accept](#) [Dismiss](#)

Direct

# Allied health professionals: Initiate, titrate, reassess

**Nonpharmacologic Preferences**

Physical Modalities	Mind Body	Touch	Exercise
E-stimulation +	Music listening +	Massage +	Yoga +
TENS +	Relaxation +	Reiki +	Resistive +
Heat/Cold +	Breathing +		Conditioning +
Compression +	Mindfulness +		Tai Chi +
Kinesio taping +			

Initiate

**Brain**

Shift: Previous **Current** Next | Show:  Meds

Add: Reminder

Prior 11/5/19 0600 0700 0800 0900 1000 1100 1200 1300

Altman, Mark  
65 y.o. / M  
MRN: 7-289-888  
DOB: 9/29/1954

Service / Primary Team: RST CVD ADMIT/TRIA...  
Code: FULL  
Primary Problem: Cardiac Device Infection...  
Allergies: Adhesive Tape-silicon...

854-P

Orders

PRN

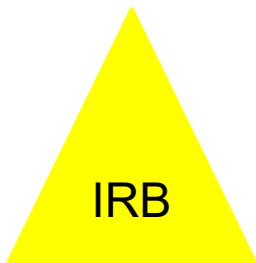
Notifications

Altman, Mark  
Assessments  
0926 Re-assess Pain  
Flowsheets

+ Task

Titrate & reassess

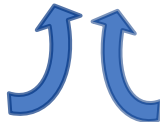
NIH Collaboratory/Heal  
Initiatives/NIA&NICHD



**Trial Coordination**  
Tilburt/Pacyna/Robinson



Cheville/Gazelka



**Site Champions**  
FL AZ MCHS

**Modalities**  
(Fulton/Hare)

**Data**  
(Haberman/  
Rhodes+Hare)

**Practice  
Engagement**  
(Leppin/Hare)

**Conversation  
Guide**  
(Hargraves/  
Rhodes)

**Hospital &  
Post-Surg**  
(Hooten/Hare)

**Epic**  
(Cheville/  
Rhodes)

ME&IC

# 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

Barrier	Level of Difficulty*				
	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		

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

# Thanks!



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



MAYO  
CLINIC



Thank You

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