

NOHARM

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

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• NIH Collaboratory

Health Care Systems Research Collaboratory



NIH · Helping to End Addiction Long-term



National Institute on Aging



Stepped wedge, cluster-randomized trial

- Population-level
- Waiver of consent
- Target enrollment 80K with ~38K accrued



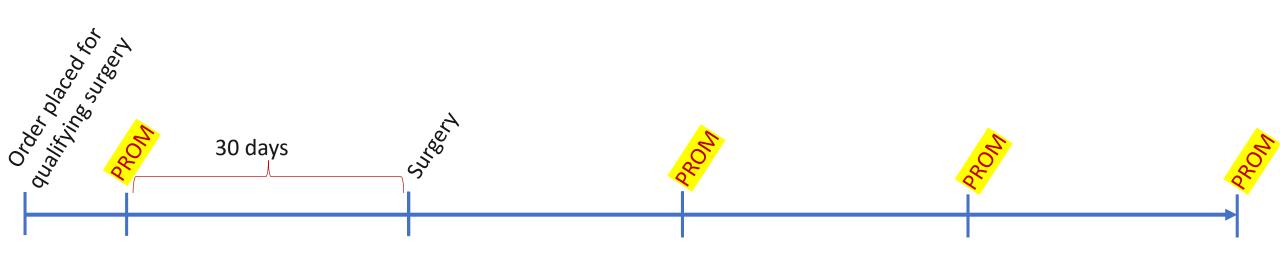
	Tranche 1 Rochester Cardiac, C-Section Florida Ortho Eau Claire Ortho, Colorectal, Gyn, C-Section La Crosse Gyn, C-Section	Tranche 2 Rochester Ortho, Gyn, Lung Arizona Lung, Cardia Mankato Colorectal	Tranche 3 Rochester Colorectal Florida Transplant Arizona Colorectal, Gyn, Transplant	Tranche 4 Florida Colorectal, Gyn, Lung, Cardiac Eau Claire Lung, Cardiac Mankato C-Section	Tranche 5 Rochester Transplant Arizona Ortho Mankato Ortho La Crosse Ortho, Colorectal
Control Condition	Data Collection 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

Outcomes:

- EHR assessment at baseline, and 1, 2, and 3 months postsurgery
- Primary
 - Pain interference PROMIS CAT
 - Physical function PROMIS CAT
- Secondary
 - Opioid consumption
 - Anxiety PROMIS CAT
 - Healthcare utilization

EHR PROM collection for clinical trials

- Potential access to any patient, anywhere, at any time
- Requires careful specification of the right person, time, and PROM
 - Assignment triggered by event and/or characteristic(s)
 - Appropriate cadence
- Avoid competing with clinical PROMs and PROMs from other studies
- Timely discontinuation as required



PROM collection via the EHR: Challenge

- Complex assignment logic
 - Trigger events
 - Require precise parameterization
 - Robust to rescheduling, cancellations, deaths
 - Sync to ensure "lock out" rules function appropriately
 - Vulnerable to EHR perturbations
 - Trial-related build advancements
 - Cluster "go lives"
 - EHR updates

PROM collection via the EHR: Solution

- Include informaticists and <u>expert</u> EHR builders on trial team
- Ensure that entire trial team appreciates mission critical research needs to:
 - Minimize bias
 - Complete data collection
 - Reduce contamination
- Regular proxy and outcome monitoring

PROM collection via the EHR: Challenge

- Lower response rates among portal non-users
 - Demographically distinct subgroup(s)
 - More frequent point-of-care PROM collection
 - Altered cadence

PROM collection via the EHR: Solutions

- Optimize site-specific POC PROM assessment modes
- PROM collection at <u>all</u> POC encounters
- "Scavenge" PROMs collected by other studies/clinicians
- Augment EHR-collection with mailed print, IVR, etc. PROM collection

EHRs for PCT intervention delivery: Opportunity

Explanatory trials tell you what is true. PCTs tell you what to do. Ideally, when, how often, to whom, etc...

- Automate capture of intervention delivery specifics, variations, and dose
 - Anticipate and parameterize process variables
 - Leverage/adapt existing data elements
 - Create new data elements
 - "Silently" embed in clinical workflows

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.