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Describing the Determinants and Effects of Variation in the Adoption a Use of the NOHARM Pain Management Intervention Among Diverse Surgical Practices

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MAYO CLINIC

IRB Minimal Risk Protocol Template

General Study Information

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Study Title: Describing the Determinants and Effects of Variation in the Adoption a Use of the NOHARM Pain Management Intervention Among Diverse Surgical Practices

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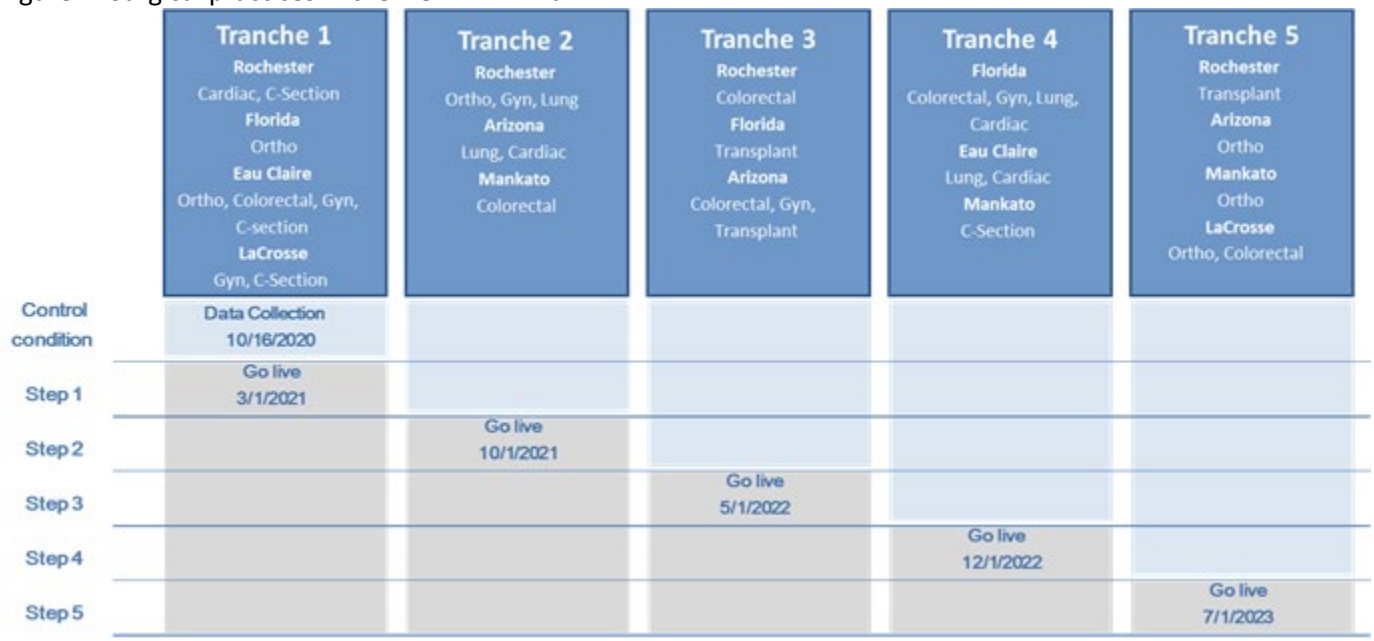
Research Question and Aims

Background and Introduction

NOHARM (Non-pharmacologic options in post-operative and hospital-based rehabilitation and pain management pragmatic trial) is a National Institutes of Health (NIH)-funded pragmatic trial testing whether patient education about non-pharmacologic pain management options, coupled with support from ambulatory and inpatient surgical care teams, improves pain and function while avoiding opioid overuse in the post-operative setting. This trial is currently being conducted among diverse surgical practices across the Mayo Clinic Enterprise as part of a stepped wedge, cluster-randomized pragmatic trial (IRB# 20-004839) with the implementation scheme depicted below (see Figure 1).

Figure 1: Surgical practices in the NOHARM Trial



As part of the NOHARM trial, all patients on the NOHARM registry (e.g. patients in all active clusters undergoing a qualifying procedure) receive an educational tool in their portals pre-operatively called the Healing After Surgery Guide. Ambulatory care teams are encouraged to inform patients about the Guide and encourage patients to access it. Patients are expected to review the guide and select their non-pharmacologic preferences from among 13 options. These selections automatically populate flowsheet rows in Epic and trigger other supports that prompt inpatient nurses to provide tailored education and the selected modalities as feasible. This trial is operating under a waiver of consent as previously approved by the Mayo Clinic IRB.

The ongoing NOHARM study is designed to determine the effectiveness of the NOHARM intervention (e.g. the patient education and clinical decision making and support bundle). Inevitably, the NOHARM intervention will be more effective in some practices and for some patients than in others. Reasons for this are multiple and complex, but important to understand. For example, if care teams within a surgical practice do not deliver the NOHARM intervention as intended it may appear less effective than it could be. Similarly, the same effect could be seen if patients are unable or unwilling to participate in the intervention fully. The ongoing NOHARM study is not designed to explore or make sense of these issues. Thus, it is unable to explain variation in key effectiveness outcomes. More importantly, the trial itself is unable to provide practical guidance on how to optimize the intervention to improve its potential for adoption and use by diverse surgical care teams and types of patients.

Study Objective and Aims

The objective of this follow-on study is to enrich the ongoing NOHARM pragmatic trial initiative with a mixed methods analysis of patient and care team factors that affect the routine adoption, implementation, and meaningful and sustainable use of the NOHARM intervention. To accomplish this objective, we will pursue the following aims:

Aim 1: Explore differences in patient engagement with the NOHARM intervention, use of non-pharm modalities, and clinical outcomes by key patient demographics, including surgical procedure type, gender, and opioid abuse risk. This aim will provide information about patient characteristics that may better predict who will use and/or benefit from the NOHARM intervention and who will not.

Aim 2: Qualitatively explore patient-level factors contributing to their ability to effectively engage with the NOHARM intervention in a diverse subgroups that adopt and use the intervention as intended and those that do not, respectively. This aim will provide information that helps us explain *why* some patients tend to use and/or benefit from NOHARM and others do not.

Aim 3: Characterize, using mixed methods, the relative fidelity and sustainability of implementation of NOHARM among ambulatory and inpatient surgical practices and test for associations with patient engagement and clinical outcomes. This aim will provide information about the characteristics of care teams that tend to adopt and maintain use of the NOHARM intervention and those that do not. It will also provide information about whether care teams play an important role in prompting patients to engage with and benefit from the NOHARM intervention.

Participants

Participants eligible for this study will be patients on the NOHARM trial registry (e.g. patients that were automatically assigned to receive the NOHARM intervention as part of their surgical care) and/or their charts and members of their care teams, including nurses, doctors, physical therapists, nurse practitioners and physician assistants, and medical assistants.

Aim 1 will exclusively use existing, Epic-based datasets and reports to conduct passive, observational secondary analyses using existing variables from medical record. For this aim, no participants will be directly contacted. For Aims 2 and 3 we will use qualitative and survey methods and will recruit a purposeful sample of patient and care team member participants, respectively. Details about these procedures and samples are outlined below.

Procedure and Methods

Aim 1: Explore differences in patient engagement with the NOHARM intervention, non-pharm modalities, and clinical outcomes by key patient demographics, including surgical procedure type, gender, and opioid abuse risk.

We will create Epic reports that combine all key variables for this aim. Specifically, reports will list all patients on the NOHARM registry, along with their age, sex, procedure type, surgeon, surgery location, insurance type, home zip code (for rurality), portal status (user vs non-user) and whether the patient interacted with the Healing After Surgery Guide. For patients that interacted with the Guide, the reports will also include opioid abuse risk (calculated from patient-reported outcomes) and non-pharm selections made, if any. Finally, reports will also include non-pharm modalities used as self-reported in post-operative surveys and include all patients that have completed the post-op follow-up period.

We will construct a "patient engagement and fidelity" variable based on data existing in the reports (made non-pharm selections y/n, used non-pharm modality in recovery y/n) and calculate these for all patients. We will use the distribution of patients by this variable to assess for correlations with clinical outcomes collected in the NOHARM trial (e.g. changes in pain and function). We will also explore the distribution of the variable within different demographic subgroups. If important contributors to patient engagement and fidelity are identified by this process, we will conduct adjusted analyses as appropriate.

Aim 2: Qualitatively explore determinants of patients' ability to effectively engage with the NOHARM intervention in a diverse subset of patients that adopt and use the intervention as intended and those that do not, respectively.

Patient Interviews: In Aim 2, we will contact, consent, and purposively interview up to 64 patients. We will aim to distribute participants across the 32 clinical practices involved in NOHARM (approximately 2 per practice). We will identify potential participants from reports of NOHARM patients (see Aim 1) and contact them via telephone, email, and or postal mail (contact info obtained from chart) with invitation to participate in a single, 30-minute, recorded telephone or Zoom-based interview. We will collect written HIPAA authorization for patients as part of this consenting process. If the subject is agreeable, documentation of HIPAA authorization will involve the use of Electronic Informed Consent (otherwise referred to as Docu-Sign) for HIPAA authorization forms. This is an institutionally approved process for documenting consent/HIPAA authorization using an on-line process. The subject may print or electronically save the consent form, or may contact the study team to provide a copy of the consent. If the subject prefers not to use Electronic Informed Consent, the study team will utilize a paper form for enrollment of these subjects, either via mail or in-person. We will compensate interviewees for their time with $20 in remuneration. We will conduct interviews throughout the project period, spreading them out amongst currently active practices. All interviews will be semi-structured and led by a guide that focuses on 1.) understanding the patient's experience with the intervention, 2.) exploring the predisposing, reinforcing, enabling, and environmental factors that cause variation in engagement and fidelity within groups and, 3.) potential strategies for improving it. It is possible that we will not be able to recruit representative patients within all 32 surgical practices, but we will aim to recruit at least 6 patients for each of the 7 surgical

disciplines (e.g. not necessarily 2 patients from each discipline and location) across the entire sample (at least 42 total interviews throughout the study duration). We will transcribe all recordings for analysis. In analysis, through regular meetings, code book drafting revision, resolving differing interpretations by consensus, memo summarization, and subsequent synthesizing into themes, we will categorize themes that characterize and distinguish high and low fidelity NOHARM engagement within and between patient groups.

Aim 3: Characterize barriers and facilitators to implementation of the NOHARM intervention by inpatient practices and compare these amongst high and low fidelity practices

We will explore barriers and facilitators to implementation of NOHARM in the inpatient setting because inpatient care teams have the greatest opportunity to support the intervention. We have also created clinical decision support prompts in Epic that are specific to inpatient staff to support implementation of NOHARM.

Inpatient Care Team Interviews

To understand barriers and facilitators to implementation and adoption of the NOHARM intervention by inpatient care teams, we will conduct interviews with 2-3 key inpatient stakeholders from each surgical practice about a year after their practice's go-live. We will conduct between 64 and 96 interviews in total.

We will recruit participants to these interviews via email-based invitations to clinical stakeholders with whom we already have relationships (e.g., nursing mangers, nursing education specialists, clinical nurse specialists, and charge nurses). These video-based interviews will last 30-45 minutes and be semi-structured to gather data corresponding to the 5 Consolidated Framework for Implementation Research (CFIR) 2.0 domains: 1) innovation characteristics, 2) outer setting, 3) inner setting, 4) key roles and characteristics, and 5) implementation process. We will make adaptations to the interview guide as needed to explore salient topics. All participants will provide verbal consent to participate. Participants will receive $50 remuneration for participating in the interview, which will be given via payroll.

Analysis:
We will use a rapid analysis approach to code audio recordings to CFIR constructs, creating a data matrix for each practice's audio-recorded interviews. We will also assign each CFIR construct a numeric, valence rating for each practice to determine the strength of different barriers and facilitators. We will then compile a master matrix to identify salient themes pertaining to the different constructs for all practices.

Using a rapid analytic approach will allow us to share ongoing findings at team meetings so that findings may be used to refine intervention implementation for later tranches.

Inpatient Epic Reports:

Using procedures like those of Aim 1, we will create automated Epic reports that summarize care team fidelity to the NOHARM intervention. Specifically, we will use these reports to identify the proportion of NOHARM patients who are discharged from a practice with NPPC selections documented in flowsheet rows (yes, no). We will then rank order practices based on the proportion of patients discharged with NPPC selections to identify the top 10 and bottom 10 performing practices. The proportion of patients discharged with NPPC selections is a good proxy for inpatient care team fidelity because this data point can be reliably captured and provision of other key Healing After Surgery resources are dependent on NPPC selections being documented (e.g.,

population of Healing After Surgery Education Points and population of NPPC specific Healing After Surgery information in the After Visit Summary).

Analysis: After, we have identified the practices with the highest and lowest fidelity, we will create a new data matrix with the qualitative interview data from the 10 highest and lowest fidelity practices and identify differences in themes between the highest and lowest performing practices organized according to CFIR constructs. We will also compare the CFIR construct ratings between high and low fidelity sites to determine whether ratings (perceived barriers and facilitators pertaining to the different constructs) differentiate inpatient practices with high verus low fidelity.