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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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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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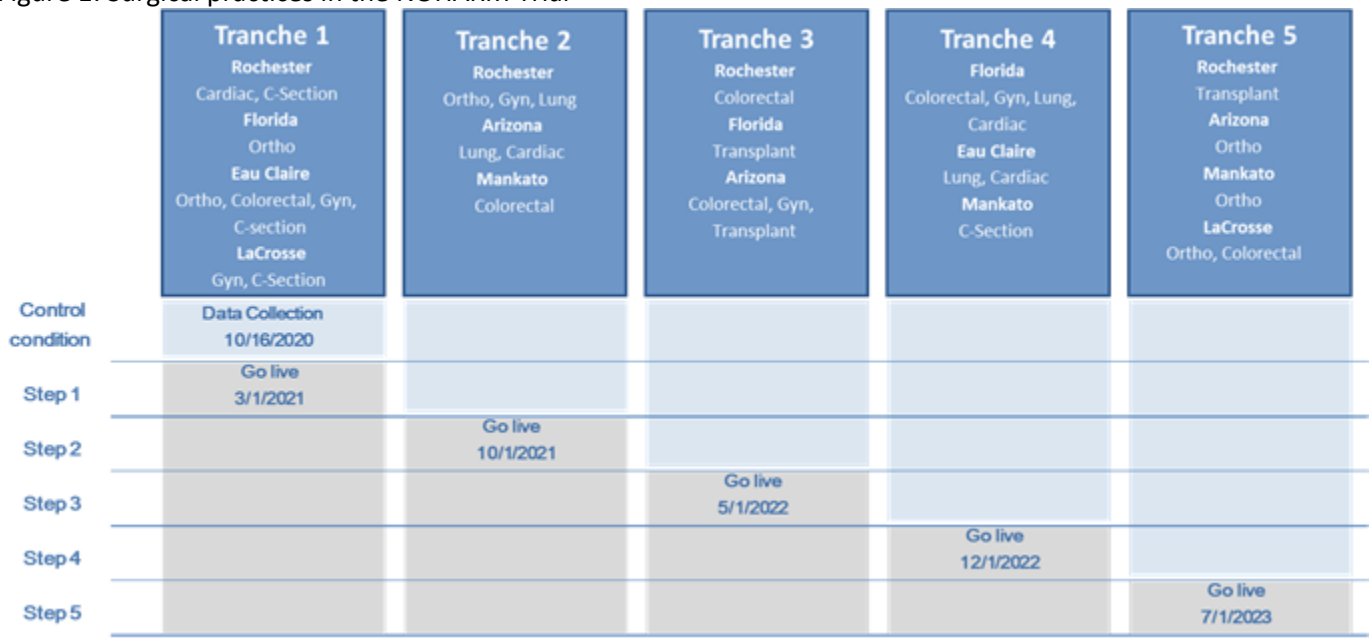
Research Question and Aims

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 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 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. We will first use a rapid analytic approach to analyze transcripts by summarizing each interview transcript under domain labels, corresponding to the interview questions. Individual summaries will be compiled into a Data Matrix to allow for comparison across interviews and identify emergent themes and differences between groups of patients, who vary in their level of engagement with the NOHARM intervention. The Rapid approach allows for ongoing learning and quick identification of any iterative improvements that could enhance the intervention for patients. The final data matrix may be uploaded to Nvivo to allow for coding and querying of codes, followed by memo summarization and discussion to arrive at consensus of themes.

Once data has been rapidly analzyed, we may return to the transcripts for more in depth analysis consisting of regular meetings, code book drafting and revision, coding of transcripts, resolving differing interpretations by consensus, running coding queries in Nvivo, 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, and may explore other key topic areas that emerge upon reviewing the qualitative data.

Aim 3: Characterize, using mixed methods, barriers and facilitators to implementing the NOHARM intervention and its potential for sustainability among surgical care teams and test for associations with patient engagement and clinical outcomes.

This aim will provide information about barriers and facilitators to implementation of NOHARM experienced by different clinical care team members (e.g., nurses, nursing leadership, physical and occupational therapy, physical and occupational therapy leaders). Data gleaned from this aim may help us understand whether care teams play an important role in prompting patients to engage with and benefit from the NOHARM intervention.

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 at least 1, but up to 2-3 key inpatient stakeholders from each surgical practice at least three months after their practice's go-live. We will conduct between 32 (1 interview per practice) and 96 (3 interviews per practice) 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 managers, 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. All audio recordings will be transcribed and de-identified.

Analysis:

We will use a rapid analysis approach to summarize transcripts by summarizing each interview transcript under domain labels, corresponding to the interview questions. Individual summaries will be compiled into a Data Matrix to allow for comparison across practices and identify emergent themes. 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. The data matrix domains may later be mapped back to to the CFIR constructs or domains the questions were designed to address so that emergent themes can be organized using the CFIR model. Constructs may also be assigned a numeric, valence rating for each practice to determine the strength of different barriers and facilitators across practices.

Once data has been rapidly analyzed, we may return to the transcripts for more in depth analysis consisting of regular meetings, code book drafting and revision, coding of transcripts, resolving differing interpretations by consensus, running coding queries in Nvivo, memo summarization, and subsequent synthesizing into themes. This will enable a more in-depth assessment of the barriers and facilitators to implementation practices experienced.

Inpatient Stakeholder Surveys

We will also give inpatient stakeholders the opportunity to share feedback on their thoughts about the intervention via a short survey consisting of mostly multiple choice questions, which should take approximately 5 minutes to complete. The survey will ask about stakeholders' role and Mayo Clinic site they work at, which will allow us to agreggrate data at the site level, but will maintain the anonymity of individual's responses. We will ask stakeholders' about their impressions about the added value and burden of the intervention, to what extent they have encouraged their staff to support the intervention, and to what extent they would like to see the intervention become part of practice. These survey responses will help us understand to what extent inpatient allied health nursing leaders (e.g., nurse managers, interim nurse managers, clinical nurse specialists, nursing education specialists) at different sites support the intervention, which is likely to impact staff's uptake of the intervention and impact staff intervention fidelity.

We will recruit inpatient allied health nursing leaders (e.g., nurse supervisors, nurse managers, interim nurse managers, clinical nurse specialists, nursing education specialists) from all 32 clinical practices participating in the trial. We will recruit up to 90 allied health nursing leaders. Nursing leaders may be recruited in person by members of our implementation team and given the opportunity to complete the survey and turn it in in person or mail back to our team via intra-clinic mail, depending on what they prefer. For those who complete the survey online, we will email them an invitation to complete the survey along with an embedded link to complete the online version (created using Qualtrics or RedCap). Completion of the survey will be taken as a form of assent. Nursing leaders may also be recruited by phone and asked to provide answers to the survey questions via a short (< 7 minute phone call) that the study team member records in the web-based database housing the survey (e.g., RedCap, Qualtrics). Those who complete the survey will receive remuneration in the form of $35 added to their paycheck, to compensate busy nursing leaders for their time.

Analysis:
All paper survey responses will be entered into the web-based platform (Qualtrics or RedCap) used to collect responses from the web-based version of the survey for those who choose to complete the survey online. We will calculate descriptive statistics from this survey at the site level (e.g., Rochester, Arizona, Florida, Eau Claire, La Crosse, and Mankato). The survey responses will help us identify sites who's leadership is more or less enthusiastic about the intervention and the prospect of the intervention being sustained in some form upon study determination. These findings will complement findings from the stakeholder surveys that seek to identify specific barriers and facilitators to implementation of the intervention on inpatient nursing units.

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 and the proportion of patients for which at least some of the Healing After Surgery education listed in the Education Tab has been delivered. We will then rank order practices based on the proportion of patients who did not have NPPC selections in their chart at the time of surgery, but were discharged with NPPC selections, and the proportion of patients who had at least some Healing After Surgery education delivered by the time of discharge to identify the top 10 and bottom 10 performing practices interviewed. 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 Healing After Surgery education points auto-populate for all patients, so we can evaluate whether they have been completed or not.

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.

Physical and Occupational Therapy

To understand barriers and facilitators to implementation and adoption of the NOHARM intervention by physical and occupational therapy teams, we will administer an anonymous web-based survey (RedCAP). The survey will take approximately 10 minutes to complete and consist of multiple-choice questions along with a few open-ended questions for therapists to provide additional feedback if they wish. We will ask staff which Mayo Clinic location they work at, but no other identifying information will be collected.

We will recruit physical and occupational therapists, by working with therapy leaders and requesting ~15 minutes on standing therapy meetings (~2 minutes to introduce the survey and ~10-13 minutes to allow time for survey completion). After introducing the survey, we will share the link to the survey in the chat so that staff who are interested in completing the survey can do so. Paper copies may also be supplied for in person meetings. For therapy leaders who prefer not to offer the opportunity to participate during a staff meeting, we will ask them to distribute an email invitation inviting staff to participate in the survey, which will contain the survey URL. We will ask that leaders share meeting attendance or staff distribution lists with our team so we can calculate a response rate, but due to the anonymous nature of the survey, we will not be able to identify which staff member chose to participate and who did not. We seek to recruit a total of n = 280 therapists.

Epic Reports: To distinguish between high and low fidelity therapy practices, we will pull Epic report data on therapists' interaction with the NOHARM therapy identifier (BPA=Best Practice Advisory) and use of the NOHARM therapy smartphrase within their documentation. We will then rank order therapy practices from highest to lowest fidelity according to the frequency by which therapists acknowledge the NOHARM BPA and the frequency with which therapists documented supporting the patient's NOHARM non-pharmacologic pain care preferences during their therapy sessions, using the NOHARM therapy smart phrase.

Analysis: We will explore differences in survey responses between high and low fidelity therapy practices identified by the Epic reports to determine whether certain barriers or facilitators were more common amongst high or low fidelity practices.