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NIH Collaboratory Ethics and Regulatory Core: Initial Consultation
Coordinated Care Pain Management Technology Implementation (CARNATION)
January 21, 2026; 3:00-4:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Anthony Domenichiello (NINDS), Rebecca Hommer (NINDS), Luke Gelinas (Advarra), Beda Jean-Francois (NCCIH), David Magnus (Stanford University), Kevin McBryde (NCCIH), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke, Caleigh Propes (Johns Hopkins University), Tammy Reece (Duke University), Damon Seils (Duke University), Jeremy Sugarman (Johns Hopkins University), Dave Wendler (NIH Clinical Center)
- Study team: Lynn DeBar (co–principal investigator), Meghan Mayhew (project director)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
Overview of the trial	Meeting attendees received the project's specific aims, research plan, and data management and sharing plan with the agenda (see supplementary material attached). Jeremy Sugarman facilitated introductions and described the purpose of the consultation. Co–principal investigator Lynn DeBar represented the CARNATION team, along with Meghan Mayhew (project director). **Project overview**: Lynn gave an overview of the project, which is supported through the NIH HEAL Initiative by a grant from the National Institute of Neurological Disorders and Stroke (NINDS) using a UG3/UH3 award mechanism. The CARNATION team will partner with a national network of community health centers to test a multicomponent implementation support intervention designed to enable community health centers' systematic use of EHR technologies for coordinating primary care–based pain care that is congruent with integrative pain management (IPM). IPM includes elements of biopsychosocial-based pain management strategies. The team's prior research showed that high-impact chronic pain is most prevalent among adults living in poverty, those with less than a high school education, and those with public health insurance, and hence they are a focus for this study. The project builds further on the team's prior research involving qualitative interviews with		

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	community health center staff and patients regarding the delivery and receipt of nonpharmacologic treatments for chronic pain in these settings. **Sponsoring institution**: Kaiser Foundation Research Institute. **Collaborators**: OCHIN, Inc; community health centers in the OCHIN Network; RAND. **NIH Institute Providing Support/Oversight**: National Institute of Neurological Disorders and Stroke (NINDS). **Study design**: The research team plans to conduct a hybrid type 3 implementation-effectiveness cluster randomized trial to test a multicomponent implementation support intervention to help community health centers use the EHR-integrated Compass Rose module in Epic to coordinate multimodal pain management. The trial will involve 20 community health centers in the OCHIN network, each with a minimum of 50 eligible patients. The clinics will be randomly assigned 1:1 to either the early intervention arm or the delayed intervention arm. In the UG3 planning phase, the research team will engage key advisors and identify the participating community health centers, tailor the health IT infrastructure and EHR tools to optimize facilitation of IPM-congruent care delivery, ensure the adequacy of the health IT infrastructure, and refine the process and outcome measures. In the UH3 implementation phase, the research team will conduct the pragmatic trial, assess impacts on pain-related functioning, and conduct a formative evaluation and budget impact analysis. **Outcomes**: The primary outcome is a clinic-level composite measure of IPM-congruent care. It is a binary measure representing whether an eligible patient received all core components of coordinated pain care within 6 months of their initial primary care encounter. To meet the criteria for this outcome, all 5 of the following must be documented in the EHR: initial pain screening and at least 1 reassessment; medication review and management; receipt of physical reconditioning services (such as physical or occupational therapy); receipt of pain-related psychological support; and evidence of IPM-care coordination, such as the use of specific CMS care coordination codes.		

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	Secondary outcomes focus on clinical impacts on the patients. The study will measure changes in pain-related functional impairment within 6 months of initiating coordinated care. This is evaluated using the following patient-reported measures: resolved high-impact chronic pain, measured by the Graded Chronic Pain Scale-Revised (GCPS-R); Pain, Enjoyment of Life, and General Activity (PEG) score; and whether patients had at least a 30% (partial response) or 50% (full response) improvement in their PEG score. The study will use the PRISM RE-AIM framework to measure implementation outcomes. David Magnus asked about the relationship between this trial and the research team's previous work in the PPACT, Back On Track, and RESOLVE studies. Lynn explained that CARNATION will assist with care coordination, rather than administer the component parts. Often this kind of IPM is done in tertiary care settings. CARNATION seeks to emulate that care coordination in a way that is tailored to what is available in community health center settings.		
Status of IRB approval	Oversight is provided by the Kaiser Permanente Interregional IRB (KPiIRB). Approval for UG3 planning phase activities was received on December 15, 2025. OCHIN's reliance agreement with KPiIRB is currently in process and is expected to be finalized by the end of January 2026. The research team intends to submit a modification containing the final UH3 trial protocol in July 2026 to ensure approval by August 2026. The research team has had discussions with the IRB about the study's rationale, focusing on the clinic-level measures and the use of EHR data rather than obtaining consent and collecting data individually from patients.		
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The research team anticipates that the project will meet the criteria for minimal risk. The intervention occurs at the clinic level, involving implementation support provided by OCHIN staff whose standard jobs include such technical and workflow services. The IPM services that patients will receive are considered part of existing standard clinical care at the community health centers. Only limited analytic patient-level datasets will be transferred outside OCHIN. Jeremy asked whether there are additional burdens, risks, or data collection activities related to clinic staff. Lynn responded that the research team is trying		

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	to ensure that the intervention is not perceived to be more burdensome for the staff in these settings. Pearl O'Rourke asked for clarification about whether data will be collected at the clinic level or the individual provider level. Megan Mayhew responded that one of the implementation support components provides reports on use; the intent is to do this at the clinic level to help clinic staff and leadership understand implementation barriers. The research team is not planning to create provider-specific reports. They will see what amount of coordinating has been done at the care coordinator level but not for primary care physicians. The care coordinators are staffed out of the clinics in ways that work for their clinical workflow. This is akin to care coordination services that OCHIN helps with routinely for other conditions. The research team will not be looking at individual physician-level data. Pearl and Luke Gelinas asked about notification to providers that the study is occurring. Lynn DeBar responded that a requirement for participating clinics is to have a physician champion for the program. Pearl and Luke expressed that, although the clinic is the object of study, there are good reasons (such as transparency) to make sure providers are informed that their sites are participating in a research study. After the meeting, Lynn provided more information in response to the question about whether individual data will be collected from care coordinators that may render them subjects. Care coordinators will be asked to provide consent for participation in formative or qualitative data collection. Consent will not be obtained for obtaining data regarding usual care coordinator activities, which are standard clinical care flow processes in the OCHIN clinics, including the audit and feedback reports planned as part of the practice facilitation process.		
Privacy (including HIPAA)	The research team will request a waiver of HIPAA authorization. Due to OCHIN network member agreements and the use of a research data warehouse, public sharing of patient-level datasets is not feasible. Aggregate data and codebooks will be shared instead. Only limited, deidentified analytic datasets will be transferred outside OCHIN to the Kaiser Permanente Washington Health Research Institute for analysis.		

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Monitoring and oversight	An independent monitoring committee of 3 or 4 experts will be established. The committee will first meet in June or July 2026 to review the protocol before UH3 submission and will meet every 6 months thereafter to monitor scientific integrity and progress and to ensure the interests and needs of the community health centers are well served. Anthony Domenichiello agreed to double-check NINDS policy to determine if a formal DSMB is required.	Double-check NINDS requirements with respect to DSMBs.	**Anthony Domenichiello**
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	Core members discussed that, as pragmatic trials increasingly target clinics rather than individuals, the traditional regulatory framework (which focuses on individuals) may need to evolve to address the system or clinic as the subject.		

SPECIFIC AIMS: Musculoskeletal pain conditions are common, chronic, and disabling disproportionally impact those of lower socioeconomic status.[1-5] Historically, often treated with opioids, recent evidence has identified numerous risks and limited benefits of long-term opioid treatment for chronic pain.[6] Current guidelines urge substantial caution and limits in using opioid treatment for chronic pain and recommend multimodal pain treatment: safer pharmacological options along with non-pharmacotherapy therapies, physical interventions, psychological approaches, and complementary and integrative healthcare, congruent with integrative pain management (IPM).[7-9] Given these treatment guidelines, healthcare leaders recommend aligning frontline care to increase patient receipt of such evidence-based treatments, while reducing opioid prescribing.[10,11]

Community health centers (CHCs), serving low-income and racial/ethnic minority patients in frequently under-resourced clinics, generally perform well in safe opioid prescribing care quality measures.[12,13] Yet providers in CHCs face substantial challenges, including time and resource constraints, in ensuring that patients also receive guideline-concordant multimodal pain management services. Most CHC patients are publicly insured or uninsured, making such services less accessible.[12-14] To mitigate this barrier, some state Medicaid programs now reimburse for an array of nonopioid pain-management services,[14-19] and expansion of coverage for chronic pain care management services is provided under Medicare 2024/2025 provisions.[19-23]

With these policy changes comes a critical need for knowledge of how to effectively support CHCs' ensure that their patients receive such services. This team's recent study of CHCs in Oregon (where Medicaid coverage of non-opioid pain management services was expanded) and California (comparison state) showed significant increases in patient receipt of pain-related health services and better patient-reported outcomes aligned with the coverage changes.[12,14,24] However, without dedicated support and resources to help CHCs systematically implement related practice changes, population-level improvement rates were modest. Clinic staff, administrators, and patients reported two key barriers to widespread adoption of recommended care models for pain: 1) their health informatics technology (HIT) infrastructure did not facilitate the provision of multimodal pain management, and 2) they lacked support to implement coordinated evidence-based pain care.

Potential solutions to these barriers are emergent. In 2022, the Compass Rose care management application was activated in the Epic electronic health record (EHR) platform shared by a national network of approximately 2,000 CHCs in 43 states. This EHR-integrated application is designed to support the care coordination services central to IPM-congruent care. However, optimizing its uptake into CHC care processes involves complex clinic-wide practice changes which require implementation support. Effective strategies for providing such support are needed. To identify and optimize such strategies, we will partner with this national CHC network to test a multi-component implementation support approach designed to enable CHCs' systematic use of Compass Rose to improve provision of coordinated primary care-based pain care. This hybrid type 3 implementation-effectiveness cluster randomized trial, the **C**oordinated c**AR**e pai**N** m**A**nagement **T**echnology **I**mplementati**ON** (**CARNATION**) study, will achieve the following Aims:

Aim 1: Use UG3 phase to: a) engage key advisors and identify CHCs to participate; b) tailor HIT infrastructure to optimize its facilitation of IPM-congruent care delivery, c) ensure adequate EHR/HIT infrastructure and data quality to conduct UH3 trial; d) refine process and outcome measures; and e) finalize study protocol. We will partner with clinicians, healthcare system leaders, and patients to ensure the implementation support strategies to be tested reflect their priorities, and with the NIH Pragmatic Trials Collaboratory to ensure a feasible and rigorous final study design.

Aim 2: Test the impact of the implementation support intervention package on CHCs' use of the tailored HIT tools for the delivery of coordinated multidisciplinary pain care among CHC patients with chronic musculoskeletal pain. This trial will randomize 20 CHCs to 2 study arms: early (intervention) and delayed implementation support (control). H2a: Providing multi-component implementation support will significantly increase use of core IPM components: medication management, psychological approaches, and physical interventions (primary outcome). H2b: Eligible patients in CHCs randomized to the early implementation support arm will demonstrate significant reductions in pain-related functional impairment within six months of initiating coordinated pain care management (secondary outcome).

Aim 3: Conduct formative evaluation and budget impact analyses to understand and explain implementation **R**each, **E**ffectiveness, **A**doption, **I**mplementation (both arms), to enhance those elements (delayed implementation/control arm) and understand **M**aintenance (early implementation arm).

The study will generate urgently needed evidence on how to make coordinated multidisciplinary pain care available to CHCs for whom limited resources present numerous barriers to the delivery and coordination of such care. Results will provide empirically based guidance on how to optimize HIT infrastructure and provide related support for its uptake to enhance the primary care-based delivery of coordinated multidisciplinary pain care services in high-need CHC populations.

3.A. BACKGROUND AND SIGNIFICANCE

Chronic pain is pervasive, and disproportionately impacts socioeconomically vulnerable populations. Chronic musculoskeletal (MSK) pain conditions are among the most common, disabling, and costly public health problems in the U.S. and a primary reason that patients seek medical care.[4] About one in ten U.S. adults experience high-impact chronic pain (HICP), defined as pain lasting ≥3 months and accompanied by at least one major activity restriction, such as being unable to work outside the home, go to school, or do household chores.[5,25] Disproportionately prevalent in underserved, low-income, rural, and racial / ethnically diverse (i.e., health disparate) populations and those with public or no health insurance, HICP – along with complicating features such as depression and medical comorbidities – is associated with elevated risk of adverse outcomes and suboptimal pain management among these patients.[5]

Multimodal integrated pain management (IPM)-congruent services improve patient outcomes. Much pain-related healthcare uses a biomedical model, assuming a singular biological cause for chronic pain and that identifying this cause will "cure" pain.[26] Yet evolving understanding of the contributors to chronic pain suggests that a biopsychosocial model that shifts the focus from "fixing" causes of pain toward improving the experiences of individuals with chronic pain and enhancing functioning is more appropriate.[4,27-29] A 2022 update to the CDC guideline for prescribing opioids for pain emphasizes the importance of individualized care and the critical role of nonpharmacologic therapies (NPT) and non-opioid multimodal treatment (i.e., NPTs and pharmacotherapy).[29] Recent systematic reviews show that a variety of noninvasive NPTs for chronic pain can improve pain and functioning without the concomitant risks of opioids.[8,9,30] In particular, exercise, physical therapy, and evidence-based psychological therapies are recommended as core components of multimodal IPM, along with medication management.[7] Several complementary and integrative health approaches (i.e., chiropractic, acupuncture, yoga, massage) also have demonstrated benefits for pain management and are often recommended parts of multi-modal IPM-congruent care programs.[8,31-34] Given this evidence, healthcare leaders have called for realigning frontline clinical care to provide coordinated access to these IPM-congruent services while reducing potentially unsafe opioid prescribing,[10,11] and public insurers, including some Medicare and state Medicaid programs, are now expanding coverage for multimodal IPM-congruent health services.[14-23]

Key barriers to facilitating patient access to IPM services could be overcome with effective health information technology (HIT) functions, and support for clinics' adoption of such HIT. Coordination of IPM-congruent services can be particularly challenging in under-resourced community health centers (CHCs), where many of the nation's most socioeconomically vulnerable patients receive primary care. Physical therapy and psychological services are typically unavailable within CHCs. Therefore, to facilitate CHC patient access to *all* core components of multimodal IPM-congruent care, CHC care teams must: conduct comprehensive pain assessment and re-assessment to guide care plan development; enable appropriate referrals; and promote ongoing bidirectional communications with and coordinate linkages to multiple external providers. Existing HIT infrastructure elements could support these coordination efforts if optimized to meet CHCs' needs; specifically, recently released EHR-based technologies designed to support general care management needs have the potential to address some of these barriers including 'closing the loop' on referrals and tracking receipt of pertinent pain services outside the CHC. But optimizing these HIT tools to support IPM-congruent care is beyond what most CHCs can do without help, and improving HIT tools does not ensure their use; the widespread uptake of such tools requires **up-front support in both HIT infrastructure and workflow redesign** to integrate care teams' use of HIT that supports IPM-congruent care provision. Few reimbursement mechanisms cover these investments, hampering CHCs' ability to use HIT for coordinated IPM-congruent care. Furthermore, care teams' uptake of HIT in IPM-congruent care involves adoption of **complex practice changes**. **Therefore, simply making this technology available in CHCs' EHR is unlikely to lead to its widespread adoption to support IPM-congruent care.** Evidence from studies of the implementation of other care programs and HIT tools, including some by our team, makes clear that CHCs' adoption of new HIT requires implementation support strategies that are **aligned with the technologies targeted for implementation** and **tailored to meet CHCs' unique needs**. Thus, there is also a need to identify implementation support strategies that effectively overcome barriers to the integrated use of HIT for pain care coordination. Identifying effective support approaches must involve co-developing and testing these strategies with CHC clinicians, staff, and patients.

Our study site is ideal for studying how to support CHCs' adoption of such technologies. OCHIN (not an acronym) hosts a customized instance of Epic, supporting the nation's largest network of CHCs on a single EHR system (see OCHIN Facilities & Other Resources). As of late 2024, 155 of OCHIN's approximately 200 member organizations have activated the care management **Compass Rose** EHR module. Epic is the most widely implemented EHR application in ambulatory care. Its novel Compass Rose module was developed to

support care coordination through EHR-integrated technologies such as registries, care planning, coordination across care teams, social risk screening, referrals to and enrollment in community programs, and tracking outcomes of these referrals over time. Compass Rose is well suited for adaptation to support IPM-congruent care coordination; OCHIN conducts similar CHC-focused Epic enhancements regularly.

OCHIN's activation of Compass Rose is the first instance of a care management-targeted integrated technology that is available across a large CHC network. We will partner with CHC clinician and staff advisors to tailor Compass Rose to optimize its support of IPM-congruent care coordination for high-need CHC patients. We will then test whether and how a set of evidence-based implementation strategies (leadership support, staff training, local champions, practice facilitation, and audit and feedback data) tailored to the needs of CHCs per feedback from these advisors enhances the adoption of the newly available Compass Rose module for IPM-congruent pain care coordination. The **C**oordinated c**AR**e pai**N** m**A**nagement **T**echnology **I**mplementati**ON** (**CARNATION**) study results will yield new, critically needed evidence on how to support CHCs' use of care management technologies in the care of patients with chronic MSK pain.

3.B INNOVATION. To our knowledge, this study is the first to evaluate an EHR-based care management tool tailored to enhance receipt of IPM-congruent health services within healthcare settings (CHCs) focused on serving diverse populations for whom socioeconomic barriers yield critical challenges to accessing healthcare. Thus, the proposed work is highly responsive to RFA-NS-24-041 objectives and to national pain care priorities. Another innovation is our emphasis on ensuring that clinic champions receive adequate time and training to prepare them to direct their clinic's adoption of practice changes related to use of the targeted HIT functions. Though many prior studies showed that champions are key to driving such change,[35,36] few have adequately considered whether that champion has the resources needed to succeed. Finally, the study is innovative in its focus on the use of practical, scalable implementation support strategies, refined through CHC partner input and deployed using existing practice improvement processes within this large national network of CHCs, enhancing the sustainability and likelihood of broader dissemination of this model for supporting IPM-congruent care. Results will provide needed, novel evidence on how to align existing EHR tools to support IPM-congruent care management, and support the widespread adoption of such tools, in primary care.

3.C. APPROACH

3.C.1. <u>Study Overview</u>. The eventual UH3 trial will be a hybrid type 3 implementation-effectiveness cluster randomized trial to evaluate the adoption of HIT-based innovations for enhancing primary care-based IPM-congruent care for patients with high-impact musculoskeletal chronic pain receiving care in CHCs. Twenty CHCs will be randomized to 2 study arms: 1) early receipt of the implementation support intervention described in Table 3 (n=10 intervention CHCs); and delayed implementation support (n=10 control CHCs). This trial design is highly appropriate for assessing implementation strategies that have real-world application, where there is policy momentum for implementation, and where the study outcomes incorporate adoption of a given technology. Hybrid type 3 trials primarily assess the effectiveness of implementation support strategies with a secondary emphasis on the effectiveness of the clinical intervention(s) being implemented on patient outcomes (i.e., not a primary outcome); such interventions' clinical effectiveness must be established before assessing their implementation.[37]

During the one-year UG3 planning phase, the implementation support strategies to be tested in the UH3 trial will be adapted through CHC clinician and staff engagement to meet the specific needs of CHCs seeking to adopt HIT functions (the EHR-based Compass Rose care management tool) to improve their ability to provide and document the provision of coordinated IPM-congruent care. A CHC clinician/staff advisor-driven adaptation process will first be applied to a bundled set of promising implementation strategies, including training, staff support, project champions, practice facilitation, and audit & feedback (A&F) (see 3.C.8.2.), which have been selected based on evidence for their effectiveness in supporting adoption of other HIT-based innovations.[35,36,38-45] In the UH3 phase we will test the effectiveness of the refined implementation strategy bundle in the hybrid type 3 implementation-effectiveness trial, as described above.

Guided by the RE-AIM framework, study outcomes will prioritize assessing patients' receipt of IPM-congruent core components collectively (primary outcome) as well as the separate receipt of the component parts, including HICP screening, assessment of pain-related functioning and patient experience to guide IPM-related service referrals, patient receipt of IPM services, and care manager utilization of HIT-embedded tools to support IPM-congruent care. The delayed control design ensures that all study clinics eventually receive the implementation support, which will both help with study recruitment and allow us to secondarily evaluate whether user feedback-driven refinements of Compass Rose tailoring and of the implementation support

strategies further improve uptake and impact in the control (delayed implementation) clinics. The delayed control design will provide a suitable CHC cohort for our budget impact analysis.

3.C.2. Setting. OCHIN, Inc. is a non-profit health center-controlled network that provides a shared Epic EHR platform for 253 member organizations (healthcare systems) comprised of more than 2,000 CHCs across 43 states. These CHCs are part of the nation's primary care safety net, and annually provide care to 6.3 million patients from health disparate populations.[46] The demographic profile of OCHIN members' patient population mirrors national estimates of patients served by CHCs, making results generalizable to similar health centers nationwide. OCHIN's centrally managed EHR and diverse membership make it a unique "community laboratory" for testing intervention impacts. In addition, OCHIN is a national leader in developing and implementing HIT/EHR-embedded digital interventions in partnership with CHC stakeholders and testing how such tools can be used to address health inequities.[47-54] Table 1 provides descriptive statistics of patients aged 19 years and older with MSK pain diagnoses who had primary care visit at OCHIN CHCs in 2023.

Table 1. OCHIN patients ≥19 yrs with musculoskeletal pain dx and visit in 2023

Patients	442,907
Female	61.9%
Race	
White	58.4%
Black	17.7%
Other	9.0%
Unknown	14.8%
Hispanic ethnicity	32.3%
Federal Poverty Level	
≤100%	65.5%
101-150%	11.1%
151-200%	6.1%
>200%	10.0%
Unknown	7.4%
Non-English	33.1%
Primary Insurance Type	
Medicaid	45.5%
Medicare	20.3%
Uninsured	17.0%
Private/Other	17.2%
Comorbid Chronic Conditions	
Hypertension	41.2%
Depression/Mood Disorders	33.2%
Anxiety Disorders	31.3%
Diabetes	21.5%
Social Needs Screening	
Food Insecurity	25.5%
Housing Instability	16.3%
Transportation	15.4%

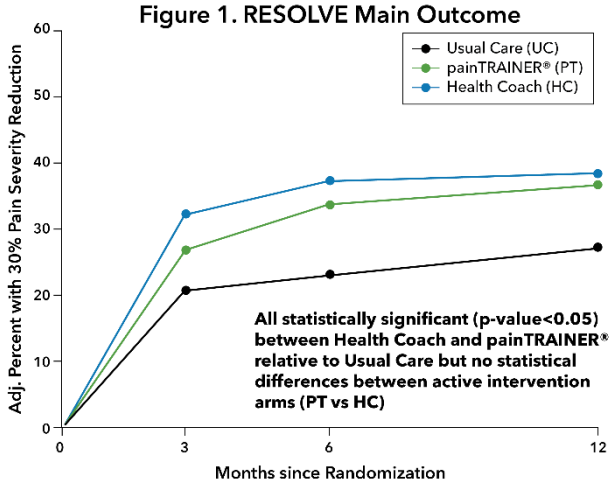
3.C.3. Relevant Preliminary Studies. The CARNATION study's concept and development were informed by the programmatic body of research outlined below. **Back On Track** is a recently completed PCORI-sponsored mixed methods study evaluating a state Medicaid reimbursement policy supporting provision of evidence based and IPM-congruent services for patients with back and neck pain. Carried out across 81 diverse OCHIN CHCs in Oregon and California (comparison state), It showed significant changes in the receipt of pain-related health services aligned with the coverage changes and better patient reported pain-related outcomes in Oregon compared to those receiving care in California (prospective cohort study involving 2,495 participants).[12,14,24] With no provision of dedicated implementation support and resources, however, changes in health service use and patient outcomes were modest at a population level across Oregon. Extensive qualitative data from the study collected from clinicians, staff, healthcare administrators and patients suggested that inadequate HIT infrastructure and lack of support for evidence-based pain healthcare service coordination were substantial barriers to CHCs optimally benefitting from such coverage changes and enhancing alignment with the tenets of IPM. **The CARNATION study is designed to address these gaps.**

Our team also conducted a pragmatic clinician-level cluster randomized trial of a primary care-embedded IPM program for patients with chronic pain on long-term opioids across three healthcare systems (**PPACT**). It found that the multidisciplinary IPM-congruent intervention resulted in significant improvements in both pain intensity and pain-related interference post-treatment, with effects sustained through 12 months of follow-up when compared to outcomes of those receiving usual care.[55] The intervention was also found to have a cost-offset such that those in the intervention had lower total follow-up costs even when accounting for intervention costs and its delivery as well as greater outcome (QALY and responder) gain,[56] suggesting the cost savings possible with primary care-based IPM services, albeit within an integrated care delivery system.

Challenges in identifying frontline behavioral health providers to provide evidence based psychological pain services in both PPACT and Back On Track led us to conduct a comparative effectiveness study (**RESOLVE**) comparing online cognitive behavioral treatment (CBT) to analogous care delivered by behavioral health specialists among 2,331 patients with high impact MSK pain from four healthcare systems across the country (44% from rural/medically underserved areas).[57] Preliminary outcomes show that connecting patients with 3 months of online CBT services (painTRAINER®) resulted in clinically significant improvements in pain-related

functioning, sustained through 12 months, that was lower than but not clinically or statistically different from the more intensive behavioral specialist coaching model (Figure 1). Here, we propose making this free, care manager-trackable online CBT program available for all CHC patients eligible for IPM-congruent services as a means to lower barriers to receipt of this core component of IPM congruent care. In addition to these studies, Dr. DeBar's relevant past work includes co-leading two additional pragmatic and implementation effectiveness trials[58,59] in which alignment with CMS service reimbursement as well as studies of HICP[5] and the revised graded chronic pain scale[60] are relevant to the proposed trial.

Figure 1. RESOLVE Main Outcome



Team members have also conducted numerous prior studies on CHCs' adoption of new technologies. Of particular relevance, Dr. Gold's **DEDICATE** study (NCT06489002) is focused on Compass Rose implementation targeting social service referrals to address patient-reported adverse social determinants of health; its ongoing learnings on how Compass Rose can be modified and supported will inform all aspects of the work proposed here. Her prior work on CHCs' adoption of clinical decision support tools, social risk-related EHR tools, and care coordination tools all provide highly useful guidance on how to support CHCs' adoption of practice changes.

3.C.4. Research Team. This project builds on established partnerships between the scientific investigators and the four participating research institutes: OCHIN, the two Kaiser Permanente (KP) Research Centers (KP Center for Health Research; KP Washington Health Research Institute), and RAND. Collectively these investigators have a long history of multisite pragmatic and implementation trials, policy-focused trials, and multimethod observational studies, many targeting patients with pain conditions. Dr. **DeBar (co-PI)** has led numerous multi-site studies focused on primary care-based pain care including large pragmatic trials, hybrid implementation-effectiveness trials, and multimethod observational trials in multiple healthcare systems including the OCHIN network.[12,14,24,55-57,59] Drs. **Cook (co-I)** and **Herman (co-I)** have collaborated closely on several of these trials[57,59] (and with one another[61,62]) and bring deep experience in Biostatistics including being a member of the NIH Pragmatic Trials Collaboratory Biostatistics and Design core and methods expertise in large complex trial design[63-70] (**Cook**) as well as over 40 years of experience with a wide range of economic evaluation, including the cost impacts of pain-related services[71-83] (**Herman**). Dr. **Gold (co-PI)** is jointly appointed as the Director of Implementation Science Programs at OCHIN and Senior Investigator at the KP Center for Health Research. She has expertise in health services research, implementation science, informatics, and quality improvement in CHCs. Dr. Gold has led/leads multiple trials at OCHIN focused on developing and implementing EHR-based clinical decision support tools in CHCs, including testing the effectiveness of: 'translating' an EHR-based quality improvement initiative into CHCs,[47,84-86] implementation strategies to increase CHCs' adoption of this intervention,[41,42,87-89] HIT tools targeting cardiovascular disease risk,[47,49,51,90-94] and targeting social risk-informed care.[48-51,53,95-97] She now co-leads the DEDICATE study (NCT06489002) on the implementation support needed to enable CHCs' use of the same Epic tool (Compass Rose) of focus here; in DEDICATE it is used to connect patients with social risks to community services. Ms. **Gunn** (co-I) is a Research Scientist at OCHIN with expertise in medical anthropology, implementation science, and health information technology who has led qualitative research on Dr. Gold's and other OCHIN-led projects (including DEDICATE).[51-54] Ms. Gunn brings deep experience to understanding EHR functionality to address patient social and behavioral needs in these settings. Dr. **Carney**, a primary care internist and medical informaticist at OCHIN, brings deep and lengthy experience in leading informatics-based quality improvement initiatives aiming to address health disparities and support the use of HIT that provides evidence-based clinical content and improves care team wellness in CHCs. In addition, two clinical researchers with expertise in pain management, will serve as consultants / advisors to the study team: Dr. Natalia **Morone**,[98-100] who is also a practicing primary care provider, and Dr. Julie **Fritz**,[101-105] a physical therapist. Both have substantial trial experience and have collaborated with Dr. DeBar previously. **Our team collectively** has expertise in designing and conducting pragmatic and hybrid trials focused on primary care-based provision of services using EHR-derived support tools. This includes expertise in core clinical domains of focus in this study (behavioral health [DeBar], primary care [Carney and consultant Morone], and physical therapy [consultant Fritz] as applied to care for chronic pain) as well as important foundational research expertise (applied clinical trials expertise,

implementation science, medical informatics, pragmatic qualitative/mixed-methods research, biostatistics, and costing expertise) targeting improvements in healthcare services for patients with chronic pain, including in the types of healthcare systems of focus for this study.

3.C.5. Conceptual Model. The guiding conceptual model for the development of the intervention and study outcomes is the Integrated Technology Implementation Model (ITIM).[106,107] The ITIM blends key features of technology acceptance and implementation science frameworks to describe the internal and external contexts, and guide the implementation activities and variables, that influence technology adoption. This model is used to develop, apply, and evaluate HIT interventions using implementation strategies in multi-tiered contexts.[107-111] We draw from the PRISM framework to complement ITIM concepts because, although at its core this is an-HIT driven implementation study, the complexity of delivering comprehensive IPM-congruent services must address further contextual factors affecting CHC clinical workflows and care processes. Table 2 (below) outlines how the ITIM model and PRISM elements are applied.

3.C.6. Community Partners/Key Representative Engagement. This study was approved by OCHIN leadership, as it supports patient health outcomes and improved CHC clinical operations for whole-person care, and positions CHCs to provide IPM-congruent care that Medicare and many state Medicaid programs reimburse. We will engage CHC key representatives (Aims 1,3) through interviews, guided tours of the technology, and co-development workshops, and observing implementation team meetings and other fieldnotes on barriers and facilitators to use of the Compass Rose HIT platform to optimize the provision of IPM-congruent patient services. Further, we will conduct interviews with patient partners to optimize relevance and accessibility of all patient-facing processes and IPM-related clinical support materials. **CHCs are appropriate community partners** as they provide comprehensive patient-centered care which can include direct provision of enabling services or provide referrals to needed services for ongoing IPM-congruent selfcare physical conditioning, stress reduction, and psychosocial support options. In addition to working directly with CHC study advisors and partners, the study will utilize existing OCHIN communication mechanisms as follows. OCHIN's Clinical Operations Review Committee (CORC), comprised of clinical leaders from OCHIN's member CHCs, provides input on all proposed EHR refinements and strategies. The CORC has stated commitment to the proposed study and will be engaged throughout the study to review progress, solicit input (e.g., review recruitment messaging, interview questions, etc.), and disseminate study findings. Additionally, we will engage OCHIN's Patient

Table 2: ITIM and select PRISM concepts mapped to study approach

Concepts	Applied in study	Description
INNER CONTEXT		
Technology adoption	Primary outcome	Evidence of Compass Rose-enabled pain-related assessment, referrals, receipt of IPM-congruent services is primary study outcome (Aim 2a)
Implementation	Intervention	Refinement and test of implementation strategies (Aims 1 & 3) will address both clinical (PRISM) and technology-driven facilitators and barriers (ITIM) to align clinic environment, needs, and policies with optimization of CR HIT tool and workflow processes to support IPM-congruent care
Technology & Interfacing systems	EHR application targeted by intervention	Compass Rose technology will be optimized to facilitate the support of IPM-congruent care and ensure linkages between IPM providers are user friendly and patient care needs are seamlessly integrated and displayed in EHR
Workflow old	Analysis	Partnership with community partners/key representatives to assess old workflows and identify areas for optimization of IPM-related clinical workflows (Aim 1)
Workflow new	Intervention	Practice facilitation is a key implementation strategy in intervention (Aim 2a)
Users (adopters)	Analysis; Outcome	Understanding of user needs will inform refinement of intervention (Aims 1 & 3); user adoption is critical to primary study outcome (Aim 2a)
Leadership	Intervention	Championship is a key implementation strategy in intervention (Aim 2)
Communication	Intervention	Implementation support by Practice Coach, Champion, and Trainers are key components of the intervention, supported by audit & feedback data (Aim 2)
OUTER CONTEXT		
Accreditation / Regulation / Guidelines	EHR application intervention targets	e.g., AHRQ evidence reviews and related treatment recommendations (Aim 3)
Policy & Economic environment	Outcome	CMS (Medicare/Medicaid)-driven reimbursement for IPM management and component pain-related services (Aim 3)
Facilitators (boundary spanner)	Intervention	Community partner/key representative-driven strategies to improve provision and coordination of IPM-congruent services consistent with evidence-based reviews and related treatment recommendations (Aim 3)
Vendor	EHR application / tools intervention targets	Epic is an EHR vendor and tool developer that supports the operationalization of clinic-external service linkages within EHR systems

Engagement Panel, a standing national panel of CHC patient and caregiver representatives, in the UG3 preparatory year and in the UH3 trial to seek their input on framing results and translating findings into practice

3.C.7. Aim 1/UG3 Clinical Trial Planning Phase. During Phase 1 (UG3) we will complete the milestones described below (including partnership with the NIH Pragmatic Trials Collaboratory Research Coordinating Center and working groups when warranted) to ensure readiness for the successful implementation of the full trial during the UH3 phase (see Figure 2 and Section 3.C.8.2./Table 3 for planned trial implementation strategies).

3.C.7.1. Establish key representative/advisory group structure to advise study team and co-refine implementation processes for optimal support of primary care-based IPM congruent services. We will convene the advisory group by recruiting 10-12 individuals with diverse perspectives and expertise, including CHC clinicians and staff with experience providing IPM-congruent care, clinical specialists in the treatment of pain, and those with IPM policy knowledge at state and federal levels. After establishing this group, we will conduct semi-structured interviews to understand current approaches, context, and barriers to delivering IPM-congruent care, including a focus on HIT infrastructure that supports the coordination of such care. Identifying unmet needs is a cornerstone of human-centered design, a problem-solving framework that centers individuals with a vested interest in the intervention development process.[112,113] Using human-centered design to develop and implement interventions can increase their impact and sustainability.[114-116] Rapid analysis[117,118] informed by key ITIM domains will inform subsequent development activities in iterative cycles throughout Phase 1. The advisory group structure will be maintained throughout the UH3 phase.

3.C.7.2. Tailor core health IT (Compass Rose) infrastructure for IPM care coordination, finalize all other implementation support interventions elements (Table 3 shows the currently planned supports to be refined), and finalize related study materials. In a series of co-development workshops, the advisory group and study team members will engage in brainstorming solutions that would optimize existing HIT infrastructure for the coordination of evidence-based IPM care and identify/refine the implementation strategies likely needed to support such HIT's integration into clinic workflows. The core intervention will involve **refining the existing Compass Rose tool**; we anticipate making minor customizations to the core Compass Rose program to enhance its functions related to eligibility documentation, care planning, patient-reported assessment tracking, and referral navigation for IPM services. The intervention also involves additional **implementation strategies (Table 3)** including **staff training** on the tool, associated workflows, and evidence for coordinated care in pain management, as well as focused training and substantial support for **clinic champions**.[119] Refinements are expected to involve those elements as well as fine-tuning **Epic training and workflow materials** and **data audit and feedback** forms to support implementation. The study team will apply ideas from these co-development workshops to refine both these implementation strategies and Compass Rose customizations.

This interventional approach involves **resources that are available to most CHCs**, though some may vary by region and health center (e.g., staffing, availability of IPM providers, rurality, organizational readiness). To account for these differences and provide an intervention adapted to unique health center context, we will utilize **practice coaching** as a core component of the implementation intervention. OCHIN practice coaches have an established track record of supporting practice change in CHCs, and are uniquely positioned to work with EHR trainers, reporting analysts, quality advisors, and clinical subject matter experts to support health centers in the proposed work. During the UG3 phase, practice coaches will work with the project team on approach refinement, focused on how to most effectively build care teams' capacity during implementation. We will seek feedback during the development process through OCHIN's EHR Support Analyst Monthly Workgroup, Population Health Member Advisory Team, as well as the CORC (see 3.C.6. above) to enhance the likelihood of intervention feasibility and sustainability across diverse settings. We will use this feedback in addition to that from the co-development workshops to revise all implementation strategies and associated technology components in preparation for the trial.

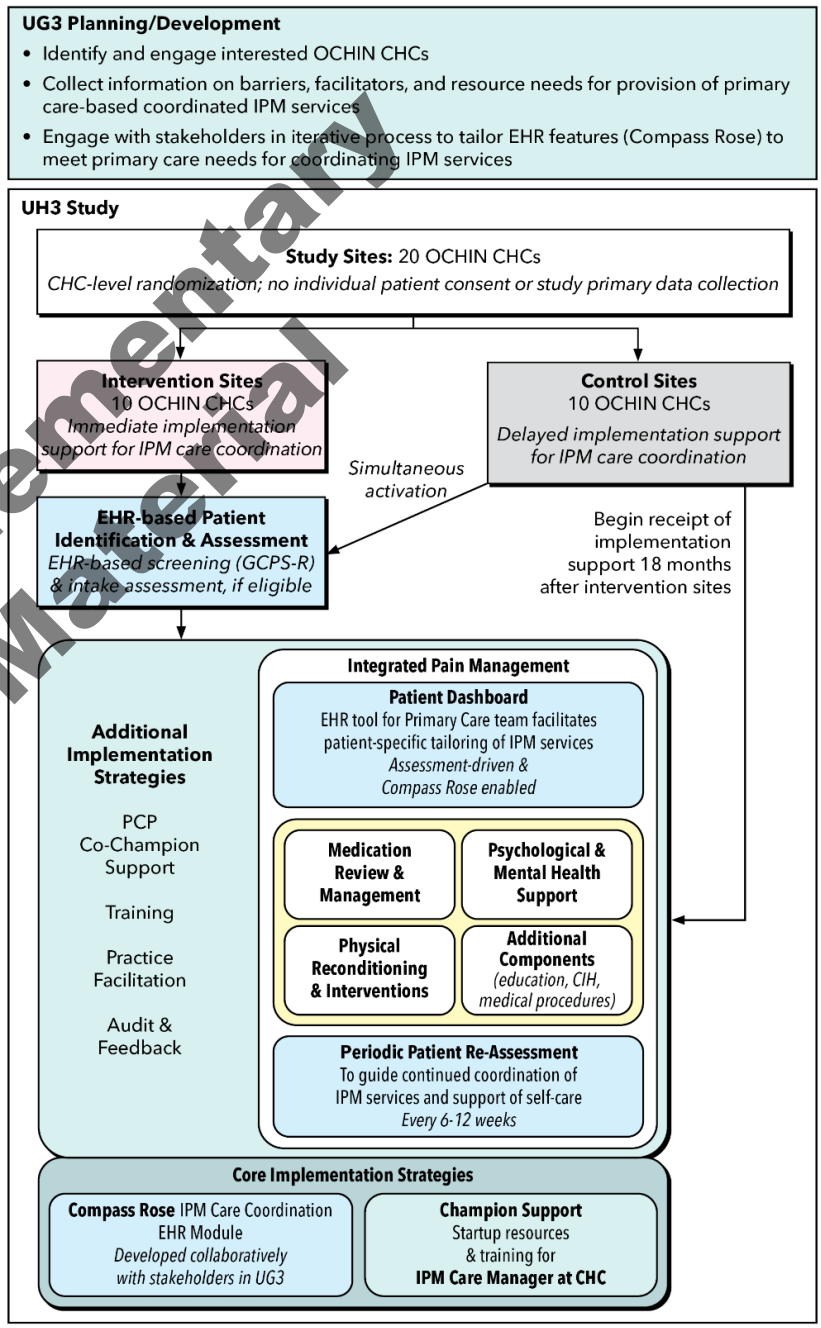
3.C.7.3. Ensure adequacy of EHR-derived clinical data for trial support and quality control processes. Because primary implementation outcomes and secondary exploratory clinical effectiveness outcomes are EHR-derived, it will be important to validate the extractability of core elements of our primary aggregate binary outcome (3.C.8.4.1 and Table 5) including: identification of pertinent pain medication orders, referrals for PT/OT and psychological support services, indicators of receipt of such care (closed-loop referrals), and patient completion of clinical pain assessments (see 3.C.8.2.1; clinical pain assessments already available for routine patient care in Epic). Further, patients eligible for screening for HICP are identified as those receiving MSK pain diagnoses during ambulatory care contacts, so we will ensure our ability to track this in real time through weekly EHR pulls. The UG3 exploratory EHR data pulls will also serve to identify important clinic

characteristics to refine analytic plans for stratification. Finally, lowering barriers for administration/re-administration of patient assessment core to IPM and summarizing such clinical information along with patient use of IPM-related service in an actionable dashboard for CHC clinician and staff use will be addressed.

3.C.7.4. Refine and pilot patient pain service assessment for routine use within participating CHCs. This EHR-based pain service assessment is intended to capture information on the IPM care that patients have received and the outcome of such services (see Appendix for draft tool). Enabling patients to describe their pain treatment and its effectiveness will help care team members coordinate their care plan approach. Supporting CHCs to collect these data is a core focus of the implementation support to be provided. We will engage patients from OCHIN's Patient Engagement Panel (PEP) to help refine and pilot the approach taken to service receipt assessment. PEP members have received care at CHCs and often partner on research activities. We will conduct cognitive interviews with eight PEP members to refine the service receipt assessment methods. Cognitive interviewing is commonly used for developing patient-reported measures and is appropriate for determining congruence of question meaning between developer and respondent.[120,121]

3.C.7.5. Finalize clinic sites for UH3 hybrid implementation-effectiveness trial participation. We will recruit 20 CHCs suited to conduct HIT-supported IPM-congruent care coordination using OCHIN's standard, effective recruitment processes. Eligible CHCs will: 1) have core IPM services (medication management, support for physical functioning, and psychological support services) available; 2) treat enough patients with chronic MSK pain-related disorders within six months to identify 50 patients with HICP to enroll in IPM-congruent care management; 3) agree to assign a clinic champion and physician co-champion to support implementation (see Table 3); and 4) express interest in enhancing IPM-congruent services (likely in states / settings with more comprehensive Medicaid / Medicare coverage of such services). We are confident that we will be able to recruit 20 CHCs from among the >2,000 OCHIN CHC members. OCHIN's clinical leaders, represented by the CORC, have committed to supporting recruitment (see Letter of Support) using standard communication methods. Further, we expect that adoption of state Medicaid initiatives[14-19] will encourage reimbursement for IPM services and that recent and expected Medicare-allowed IPM-related coverage codes[19-23] will enhance motivation for study participation. We have a successful history of recruiting CHCs for diverse research projects. Participating CHCs will receive an impact fee in addition to the rich implementation support described above.

Figure 2. CARNATION Study Overview



3.C.7.6. Other. Finalize study protocol and statistical analysis plan, finalize all plans related to regulatory oversight and prepare UH3 IRB submission, and prepare UH3 transition report. We will work with the NIH Pragmatic Trial Collaboratory and other research teams to incorporate any common practices among studies funded as part of this initiative.

3.C.8. UH3 Trial Phase

3.C.8.1. Approach overview. We will conduct a hybrid type 3 implementation-effectiveness cluster randomized trial utilizing a delayed treatment control condition among 20 OCHIN CHCs. Execution of the core components of IPM-congruent care is the primary powered study outcome. Patient IPM care receipt and pain-related functioning will be tracked for at least 50 patients per participating clinic who meet screening criteria for HICP after having ≥1 primary care visit with a MSK pain-related condition diagnosis. No primary data will be collected from patients for this study, or individual patient consent sought, as the study is focused on the implementation support needed for clinical provision of care. As such, all data used for quantitative outcomes will be limited to EHR clinical and health services data. Implementation support strategies will be refined based on learnings from early intervention arm sites (n=10) and enabled for clinics randomized to the delayed support (control; n=10) arm after 18 months. This ensures all study CHCs receive implementation support and enables evaluating the impact of implementation support strategy refinement on implementation and effectiveness outcomes. (Figure 2)

3.C.8.1.1. Randomization to early or delayed implementation will use constrained randomization[122] (controlling for baseline clinic-level covariates including mix of insurance type in the CHC, CHC baseline eligible patient sample size, rurality, average patient age, and diversity of patients seen) to conduct clinic-level 1:1 ratio randomization to the two study arms. Dr. Cook, who will have no contact with the study CHCs, will perform the randomization using R software prior to the start of the trial. This constrained randomization method ensures balance across arms in important clinic characteristics.

3.C.8.2. Intervention / bundled implementation strategies. The intervention is comprised of the bundled set of implementation strategies to support CHC IPM-congruent care management described in Table 3. These include: **tailoring the Compass Rose care management HIT tool** to enhance its utility for integrated pain management based on end user feedback and collaboration during the UG3 phase of the project, and **supporting a community health worker-level staff person to serve as IPM champion(6 months at 50%)** in each study CHC, giving them dedicated time for IPM Care Manager training and initial support to enroll and help guide staff in connecting qualifying patients (with HICP) with IPM-congruent pain services using the tailored Compass Rose tool. Additional implementation strategies include: **CHC staff training**, support of **PCP Co-Champion**, **practice facilitation** targeting workflow design, and providing weekly **audit and feedback reports** on staff use of Compass Rose for indicated patients. Table 3 describes the rationale and operationalization for these planned implementation strategies.

Table 3. CARNATION Implementation Strategies: Rationale and Proposed Operationalization (Intervention Components)

Strategy	Rationale	Proposed operational description (refined in Aim 1/ UG3)
HIT Tailoring	HIT tools tailored to clinic workflows and CHC needs enhance uptake and sustained use	In partnership with our advisory group and research team, OCHIN trainer and workflow engineer will modify available Compass Rose tools to enable IPM care coordination needs (UG3/Aim 1)
IPM Care Management Champion Support	Champions are key to practice change as they demonstrate leadership support, promote buy-in and engagement, and provide on-the-ground collegial support	Selected by CHC leadership, the IPM Care Manager will be a staff member of the CHC's quality improvement, population health, or care management teams and able to liaison with CHC management and the research team. This person will ensure that clinic staff screen patients for inclusion in IPM program, coordinate patient assessments, coordinate referrals for IPM-congruent care, and track receipt (closed referral loop). They will liaison with patients, PCPs and other IPM providers, as needed. This will be supported through trainings (below), practice facilitation, and receipt of A&F reports. UH3 includes 6 months of support at 50% time for this champion at each CHC.
PCP Co-Champion Support	Ensure structure of IPM support enables primary care team's actions & oversight related to coordination of pain management care	Selected by CHC leadership, this will be a PCP who is well-versed in IPM-congruent care and will ensure that Compass Rose individual patient care dashboards support needed PCP actions (e.g., verifying IPM-related referrals) and support the broader adoption of Compass Rose-enabled tools by primary care colleagues. This co-champion will attend training and be available to IPM care management champions to support care coordination for CHC patients.
CHC Staff Training	Users of complex new technologies require dedicated training to support IT adoption, efficient IT use, and user confidence	Trainers will conduct two, 2-hour virtual introductory trainings with IPM Care Management / Champion staff (includes 1-hour in which PCP Co-Champions participate) with additional "live" boosters available through month 3. Following this, trainers will provide training support through the intervention period (6 months) via weekly office hours and a technology support ("help desk") platform.
Practice Facilitation	Practice coaching can support change management, optimize care systems, and enhance implementation of redesigned workflows	Practice coach provides workflow transformation/change management support. We expect coach will support all related trainings and be available via weekly office hours & a technology support platform during the 6-month intervention period. CHCs can attend regularly scheduled monthly population health hours supporting IPM care management and Compass Rose.
Audit and Feedback (A&F)	A&F shows progress and provides evidence needed to: facilitate benchmarking; motivate users; and support decision-making change processes	One-page report displaying IPM patient participants, #/% with initial assessment (and re-assessment if due), #/% with referrals each for medication evaluation/management, physical conditioning and psychological support services, #/% linkages/receipt of services documented in Compass Rose (program episode/plan of care/tasks/ closed-loop referral) for each IPM-enrolled patient. A&F to be distributed weekly during active intervention implementation period.

3.C.8.2.1. Supporting IPM-congruent patient clinical assessment. There are a variety of ways that CHCs providing coordinated pain management care might choose to **assess pain and related functioning** as well as ascertain **patient experience and preferences for each care component** (medication/pain control strategies, physical reconditioning support, and psychological/mental health support). The OCHIN Epic EHR platform currently has psychometrically validated pain assessments embedded in the system for clinical use in identifying patients needing IPM services and assessing functional improvements to guide continued care. For this study, we will specifically promote the use of an existing validated pain assessment tool in the EHR – the Graded Chronic Pain Scale-Revised (GCPS-R).[60] The GCPS-R is comprised of the 3-item PEG scale (**P**ain intensity, **E**njoyment of life pain interference, **G**eneral activity pain interference), the most widely used psychometrically validated pain-related assessment tool in primary care,[123] plus three additional questions assessing pain chronicity and criteria for HICP (see Appendix). As the GCPS-R is useful to screen for HICP and to assess progress (PEG) and guide care, it is a practical assessment tool for use in primary care.

Further, because many relevant community support services and guidable self-care options (e.g., physical reconditioning through supervised exercise programs, online CBT and mindfulness pain management programs, non-prescription pain medications/topicals) are not tracked through conventional referrals and receipt of clinician-directed care in the EHR, it is important for CHC staff to understand **patients' use of various pain care services** as a means of supporting patients' ongoing care coordination and pain management planning. Part of the HIT tailoring in the UG3 phase will involve ensuring that needed clinical assessments are available and aligned with the Compass Rose IPM care coordination tool and procedures to ensure utility and feasibility of administration to guide IPM-congruent care over the 6-month intervention window (see Appendix for draft of full clinical assessment tool). Further details are provided below (3.C.8.4.2., 3.C.8.4.3., 3.C.8.5.3.) and in Statistical Design and Power section.

3.C.8.3. Data sources. **Quantitative** data will come from OCHIN EHR data (and will include IPM-pertinent health service receipt and patient pain and service clinical assessment). **Qualitative** data will come from observations of CHC implementation meetings and interviews with CHC staff and patients. Observations will be conducted during the 6-month intervention phase at each CHC in scheduled implementation team meetings. Fieldnotes will be composed following a templated form to systematically capture information on implementation activities, adaptations, and contextual factors. Documenting implementation activities and context supports clarity and reproducibility of results and informs subsequent iterations to the intervention. During the 6-month follow-up period at each CHC we will conduct semi-structured interviews with key informants at each of the 20 participating CHCs (e.g., IPM Champions, other care managers, PCP Co-Champions). We also will conduct semi-structured interviews with patients who received IPM care from each of the 20 participating CHCs. Interviews will last up to 60 minutes and be audio-recorded with permission from participants.

Table 4. Aim 2 Quantitative Outcomes per RE-AIM

Outcomes	Measurement
Reach	1) % of patients with MSK pain-related diagnosis who have new primary care encounter and receive screening for HICP; 2) of those screened, % of patients who met criteria for HICP; 3) of those who meet criteria for HICP, % for whom some component of IPM-congruent care initiated (referral for core treatment service); and 4) % of patients who decline IPM service referrals. For all above reported overall and by race/ethnicity, income, and other key demographic variables. These measures are designed to characterize program REACH at multiple levels (at each early point in the IPM program participation process).
Effectiveness (impact)	1) % of patients with documented MSK diagnosis with evidence of IPM-congruent care including: pain assessment driven (initial and at least one re-assessment) closed loop referrals for core IPM services (supporting physical functioning, psychological services, med management) at sufficient threshold so evidence based care guideline consistent (main implementation powered outcome) and each component thereof (secondary implementation outcome) 2) % of enrolled patients with a MCID in pain-related functioning as well as cost (secondary clinical effectiveness exploratory outcome)
Adoption	% of care management staff using HIT-enabled IPM care management assessment, referral, and patient tracking tools (and % of qualifying patients for whom tool used); also evidence of broader uptake by CHC care managers (apart from study supported clinic champion within study window)
Implementation	# of open tasks/activities for IPM-congruent care that remain incomplete or outstanding within 6-month treatment window for each tracked patient; whether / how the EHR tools used in unanticipated ways
Maintenance	Proportion of participating CHCs using HIT-enabled IPM care management tool beyond study window (temporally extended use) and comprehensiveness of such ongoing use (e.g., to support assessment/re-assessment, closed loop referral of IPM-related treatment services)

3.C.8.4. Quantitative study outcome measures aligned with RE-AIM are described below and in Table 4.

3.C.8.4.1. Primary (implementation) outcome. The primary outcome of the trial, summarized in Table 5 below, is a binary measure of eligible CHC patients (those identified with a MSK diagnosis) who received all of the following IPM-congruent services over the subsequent 6 months: (1) pain-related screening and at least one clinical re-assessment to monitor progress and guide ongoing pain-related support services, (2) pain-related medication evaluation and management, (3) receipt of physical reconditioning support services, (4) receipt of psychological / mental health support (can be receipt of the evidence-based online painTRAINER program, to which the study will facilitate access), and (5) indication that those providing these core IPM services have coordinated care among one another as indicated by use of 2024/2025 CMS IPM CPT codes[20-23] or otherwise evident in the EHR (final method for ascertaining to be identified in UG3 phase). All component elements of this binary outcome will be collected from OCHIN's centralized EHR data. Services may include those offered onsite as well as outside the CHC, all of which are identified in the EHR as extractable data. While we expect relatively robust use of the Compass Rose tool among the CHCs with active implementation support, which will optimize the charting of receipt of such services, the basic version of Epic Compass Rose is available to all CHCs eligible for enrollment and often used for other types of clinical case management so could be employed prior to active implementation support by the CHCs randomized to the delayed implementation condition (control). Therefore, non-use of Compass Rose for this purpose indicates a lack of care coordination, so while missing information on any core IPM components could indicate a failure to track IPM-congruent services received outside the CHC, if not evident within the EHR, it would also indicate that such pain-related care could not be coordinated. As such, missing data should be considered a meaningful outcome reflecting inability to coordinate care.

Table 5. CARNATION Implementation and Effectiveness Quantitative Outcomes

Variable	EHR Source	PC encounter with MSK pain diagnosis	Within 6 months of PC encounter
Implementation Outcomes			
Primary: Overall Composite Measure of IPM-Congruent Care Binary (0/1); 1=All five criteria met 1. Initial pain screening and ≥1 re-assessment 2. Medication review and management completed 3. Physical reconditioning services received 4. Pain-related psychological support services received 5. Evidence of IPM-care coordination	Administrative	X	X
Secondary: ***Expanded*** Overall Composite Measure of IPM-Congruent Care Binary (0/1); 1=All four criteria met 1. Medication review and management completed, ***and type/dose is consistent with EBP*** 2. Physical reconditioning services received, ***and type/dose is consistent with EBP*** 3. Pain-related psychological support services received, ***and type/dose is consistent with EBP*** 4. Evidence of IPM-care coordination	Administrative & Patient (Pain Service) Assessment	X	X
Effectiveness Outcomes*			
Resolved high impact chronic pain (binary; measured by Graded Chronic Pain Scale – Revised [GCPS-R])	Patient (Pain) Assessment	X	X**
PEG score (continuous; 3-item subset of GCPS-R)		X	X**
MCID (≥ 30% / ≥ 50% improvement) in PEG score (both binary)***		X	X**

EHR=electronic health record; MSK=musculoskeletal; PC=primary care; IPM=integrated pain management; MCID= minimum clinically important difference; EBP=evidence-based practices

*Only for those identified with high impact chronic pain at screening aligned with initial PC encounter with MSK diagnosis

**Expect multiple patient assessments completed in 6- month active implementation phase to guide care, for effectiveness outcomes utilizing assessment as close to end of 6-month care management intervention window as possible

*** ≥30% = partial clinical response, ≥50% = full clinical response

3.C.8.4.2. Secondary and tertiary / exploratory (implementation) outcomes. Table 5 includes an expanded overall composite measure of IPM congruent care implementation outcome that additionally considers services identified through the patient (pain service) assessment as well as consistency of the specific type/dose of IPM component service with evidence-based practices. Further, we will disaggregate and describe differences across the early and delayed implementation arm in receipt of each component part of IPM-congruent services including: (1) initial pain screening and clinical re-assessment, (2) medication evaluation / management, (3) physical reconditioning-related care, (4) pain-related psychological support, and (5) evidence of IPM care coordination. For components 2-4, referrals, receipt of care, and the consistency of specific service type/dose with evidence-based care will be summarized. Further, we will explore receipt of optional IPM services among patients in study CHCs including complementary and integrated health services (acupuncture, chiropractic care, massage), and pain-related procedures/devices (i.e., injections, TENS units). These disaggregated IPM-relevant services are summarized in the Statistical Design and Power section.

3.C.8.4.3. Secondary (effectiveness) outcomes. Administration of the IPM patient pain assessment (GCPS-R/PEG) will be encouraged for HICP screening among all patients with MSK-related primary care visits in all enrolled CHCs from the beginning of the trial, regardless of CHC randomization status (early or delayed). We will assist CHCs in encouraging its completion by potentially eligible patients by auto-sending the questionnaire

through the Epic patient portal (MyChart) for all patients who have an ambulatory care contact with a qualifying MSK diagnosis during the study window as well as consider practice alerts for point of care administration of such during the primary care visit. For patients who complete the pain assessment and meet HICP criteria, a re-assessment will be automatically sent via MyChart 5-6 months after completion of the first assessment. We expect that this will be the primary mode of reassessment for those in the delayed implementation (control) CHCs and will target re-assessment as close to the end of the 6-month care management intervention window as possible for patients in all CHCs.

To evaluate pain-related effectiveness (secondary) outcomes, we will include data on any CHC patient for whom two instances of the GCPS-R have been collected over a 6-month window of care – the first instance reflecting the initial high impact chronic pain screening and the second closest to six months following the initial screening to reflect the impact of receipt of IPM services over the study period. Adequate data among patients receiving services at both intervention CHCs in the early implementation support arm as well as those in CHCs randomized to delayed implementation support will allow us to compare changes in GCPS-R (resolved high impact chronic pain) and PEG scores across study arms. While data from patients receiving services in CHCs randomized for delayed treatment support may be limited, we can also evaluate the proportion of patients whose change in PEG scores are consistent with minimal clinically important difference (MCID; a patient-centered concept that measures the smallest change in a clinical outcome that a patient generally perceives as important – 30% improvement indicating a partial response and 50% for full response[124-126]). Finally, budgetary/cost-related outcomes will also be collected (see Statistical Design and Power section for more information). **While there are potential limitations with each of these effectiveness outcomes, collectively they will provide important information about the effectiveness of the implementation support on patient outcomes and cost of care and as such, provide an important enhancement to our primary implementation (powered) outcome.**

3.C.8.5. Power Analyses, Statistical, Mixed Methods, and Budgetary Analysis Plan.

3.C.8.5.1. Sample size. This study is designed to have at least 90% power to detect a 10% improvement in the difference in the percentage of patients who receive the requisite core IPM-congruent services within six months of their qualifying primary care encounter (primary outcome) among CHCs randomized to intervention (early implementation support) arm versus control arm (delayed support). We varied the CHC-level intra-class correlation (ICC), to account for cluster randomization; to be between 0.01 and 0.05, we conservatively assumed 50 patients per clinic (>50 expected) and ranged the proportion with the composite outcome in the control CHCs to be 0.05, 0.075, and 0.10 (in the UG3 phase we will update with enrolled CHC data where available). With 20 CHCs randomized (10 per arm), across most of these scenarios, we have 90% power to detect a 10% difference. See Statistical Design and Power section for more details.

3.C.8.5.2. Primary implementation outcome analyses. To assess if the IPM care coordination improved a patient's documented receipt of the core IPM-congruent services (composite primary outcome) we will estimate an adjusted relative risk (RR) of the composite outcome among patients who have a qualifying MSK encounter in the 6-month intervention window in CHCs randomized to the early- (intervention) versus delayed-implementation (control) arms. We will apply a modified Poisson regression model using generalized estimating equations to account for cluster randomization.[127] We will use a bias-corrected sandwich estimator for small number of clusters.[128] We will adjust for constrained randomization cluster-level variables (e.g., mix of insurance type in the CHC, CHC eligible patient population size, rurality, average patient age and racial/ethnic diversity of patients receiving care at CHC) and patient-level demographics (age, sex, insurance coverage type, number of pain conditions, mental health diagnoses, federal poverty level, and patient language). See Statistical Design and Power section for more details.

3.C.8.5.3. Quantitative effectiveness analyses (Aim 2b). To assess if the IPM care coordination improved the rates of patients resolving high impact chronic pain, or reducing pain, at 6 months post-qualifying MSK encounter among those with high impact chronic pain, we will conduct an analysis similar to the implementation outcomes primary analysis, but further account for response bias due to not completing the initial pain assessment and loss-to-follow-up. See Statistical Design and Power section for more details.

3.C.8.5.4. Mixed methods approach and analysis (Aim 3). We will conduct formative evaluations to understand, describe, explain, as well as enhance (for the delayed support/control cohort of CHCs) all quantitative results using the RE-AIM framework to understand Reach, Effectiveness, Adoption, Implementation, and Maintenance and use a parallel mixed method design for combined analysis of quantitative and qualitative data. Qualitative data will be analyzed following a rapid analytic approach informed by domains from the study's guiding conceptual frameworks. Rapid analysis is an effective method for assessing the intervention and producing

contextually rich findings to inform implementation activities.[117,118] Analysis will complement and explicate quantitative implementation and effectiveness analyses by providing a rich understanding of the mechanisms by which the implementation strategies wield change, for which populations, and in which setting.[129] During the data collection and analysis process, framework-informed summary documents will be prepared and the data further distilled in matrices. The multi-disciplinary study team will review emerging themes and concepts from the data to encourage iterative dialogue, support interpretation, and identify potential refinements to the intervention. Following a similar engagement approach to that used during the UG3 phase, participating CHCs, advisory group members, PEP members, and OCHIN workgroup attendees (see 3.C.6) will review and provide feedback on interim mixed methods results summaries to ensure interpretive rigor and strengthen validity. These engagement methods and subsequent refinement of Compass Rose tailoring and clinical workflows, which will be implemented in the control arm CHCs, will be essential for developing an intervention that aims to enhance implementation, patient effectiveness outcomes, and reduce disparities in pain management.[130] Mixed methods approaches are vital in assessing processes and identifying areas for improvement.

3.C.8.5.5. Cost/Budgetary Analyses details are included in the Statistical Analysis and Power section.

3.C.9. Potential Challenges and Solutions. Our previous experience conducting large-scale effectiveness, implementation, and pragmatic trials – many on behavioral pain interventions, with some of the same partners – suggest the proposed study is logistically feasible. Nonetheless, we considered several potential challenges in designing this study. The first involves generalizability. OCHIN CHCs share an Epic EHR platform. While some CHCs use other EHRs, Epic is increasingly the EHR of choice across large CHC networks as well as other ambulatory care settings, strengthening findings' replicability (and the ability to share the tailored HIT Compass Rose IPM module); furthermore, implementation principles unrelated to EHR use specifically will also be identified and reported. In addition, while other care management technology products are available, Compass Rose is the first seamlessly integrated EHR module designed to meet the unique, complex needs of care managers providing care to health disparate patients, positioning it for widespread adoption. While this study does not address factors that may affect CHC participation in IPM-congruent care coordination such as funding, staff retention, and other priorities, its longitudinal data collection will account for the effect of policy and/or payment drivers, including increasing state Medicaid and Medicare reimbursement allowances for IPM-congruent services and their coordination. Further our qualitative data collection and analyses will enable assessing perceptions of the extent to which these factors impact IPM care provision, use of Compass Rose, etc. Additionally, our delayed implementation control design will allow us to evaluate changes across time as policy refinements occur and these CMS-driven IPM-congruent care reimbursement options mature. Following our conceptual model, we will work with our community partners to identify internal and external factors outside the study scope that may influence outcomes, for consideration in results interpretation. Finally, while we considered conducting an implementation-only study (our primary powered outcome), we elected to include clinical effectiveness outcomes, despite the potential limitations with each of these effectiveness outcomes, as they will collectively provide important information about the effectiveness of the implementation support on patient outcomes and cost of care and, as such, provide an important enhancement to our primary implementation (powered) outcome.

3.C.10. Dissemination. In addition to publishing in peer-reviewed journals and scientific meetings, we will present results to OCHIN members via standing Committee meetings (see 3.C.6) and to CHCs and CHC networks at national CHC meetings. We will also develop and share a white paper on lessons learned for implementing integrated technology for IPM-congruent care provision, including automated processes for patient screening and assessment, referrals to IPM-congruent services made through clinic-community linkages and receipt of such services, and the complement of broader pain-related resources we expect patients to report and CHCs to rely on in sustaining patients' long-term management of their pain.

3.C.11. Summary of Strengths. We have a strong team of investigators with a long history of successful collaboration conducting large and multisite randomized pragmatic and implementation trials that focus on EHR-enabled interventions and interventions embedded in primary care settings. The proposed study builds on our programmatic body of research. The study is further strengthened by its novel use of HIT infrastructure to support frontline care mangers in typically low-resourced settings to provide personalized IPM-congruent support to the diverse patients served in CHCs. Conducting the study in partnership with OCHIN, the EHR provider for a national network of CHC organizations, using infrastructure and tools routinely used in supporting such clinics increases the likelihood that the intervention could be adopted, sustained, and spread if it proves successful. Dissemination of study results has the potential to improve IPM-congruent care and advance health equity for low-income and racially/ethnically diverse populations cared for across thousands of CHCs.

References

1. Keralis JM. Pain and Poverty: Disparities by Poverty Level in the Experience of Pain-Related Interference. *Pain Med.* 2021;22(7):1532-1538.
2. Mokdad AH, Ballestros K, Echko M, et al. The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. *Jama.* 2018;319(14):1444-1472.
3. Dieleman JL, Cao J, Chapin A, et al. US Health Care Spending by Payer and Health Condition, 1996-2016. *Jama.* 2020;323(9):863-884.
4. Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research.* Washington DC2011.
5. Dahlhamer J, Lucas J, Zelaya C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2018;67(36):1001-1006.
6. Busse JW, Wang L, Kamaleldin M, et al. Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-analysis. *Jama.* 2018;320(23):2448-2460.
7. Skelly AC, Chou R, Dettori JR, et al. AHRQ Comparative Effectiveness Reviews. *Integrated and Comprehensive Pain Management Programs: Effectiveness and Harms*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2021.
8. Skelly AC, Chou R, Dettori JR, et al. AHRQ Comparative Effectiveness Reviews. *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020.
9. Skelly AC, Chou R, Dettori JR, et al. AHRQ Comparative Effectiveness Reviews. *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2018.
10. National Academies of Sciences E, Medicine, Health, et al. The National Academies Collection: Reports funded by National Institutes of Health. In: Stroud C, Posey Norris SM, Bain L, eds. *The Role of Nonpharmacological Approaches to Pain Management: Proceedings of a Workshop*. Washington (DC): National Academies Press (US); 2019.
11. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. *JAMA.* 2016;315(15):1624-1645.
12. Muench J, Hoopes M, Mayhew M, et al. Reduction of Long-Term Opioid Prescribing for Back Pain in Community Health Centers After a Medicaid Policy Change. *J Am Board Fam Med.* 2022;35(2):352-369.
13. Oldfield BJ, Becker WC. Improving Guideline Adherence for Opioid Prescribing in Community Health Centers. *Pain Med.* 2020;21(9):1739-1741.
14. DeBar L, Mayhew M, Wharam M, et al. *A Naturalistic Experiment Evaluating the Impact of Oregon Medicaid Treatment Reimbursement Changes on Opioid Prescribing and Patient Outcomes Among Adults with Back Pain- A Final Report.* Patient-Centered Outcomes Research Institute (PCORI);2024.
15. Maine Legislature. An Act to Provide for Alternative Pain Treatment before Treatment with Opioids. 2024; https://www.mainlegislature.org/legis/bills/bills-129th/billtexts/SP031401.asp.
16. US Pain Foundation. Massachusetts passes landmark legislation that includes help fo pain patients. 2018; https://uspainfoundation.org/news/massachusetts-passes-landmark-legislation-that-includes-help-for-pain-patients/
17. Donovan E, Ranney ML, Patry EJ, McKenzie M, Baird J, Green TC. Beliefs About a Complementary and Alternative Therapy-Based Chronic Pain Management Program for a Medicaid Population. *Pain Med.* 2017;18(9):1805-1816.
18. Lentz TA, Gonzalez-Smith J, Huber K, Goertz C, Bleser WK, Saunders R. Overcoming Barriers to the Implementation of Integrated Musculoskeletal Pain Management Programs: A Multi-Stakeholder Qualitative Study. *J Pain.* 2023;24(5):860-873.
19. Ling S, Nagel D, Steinberg C. (2024, June 24). *Health policy & advancing value-based pain care solutions.* Pain Collaborative to Advance Equitable Value-based Solutions, virtual meeting. Slides accessed on October 20, 2024, from https://healthcarecollaboratives.com/wp-content/uploads-2024/07/Pain-Collaborative-Mtgh-6-24-24.pdf
20. CMS. Calendar Year (CY) 2024 Medicare Physician Fee Schedule Proposed Rule. CMS.gov; 2023.
21. CMS. Calendar Year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule. CMS.gov; 2024.
22. Bassano AG, Z; Kirby, K; Kramer R. CMS's newly released CY 2025 Medicare Physician and Hospital Outpatient Proposed Rules include proposals supporting primary care, care coordination, and

increased access to care for Medicare Beneficiaries. *Health Management Association.* 2024; https://www.healthmanagement.com/blog/cmss-newly-released-cy-2025-medicare-physician-and-hospital-outpatient-proposed-reules-include-proposals-supporting-primary-care-care-coordination-and-increased-access-to-care-for-medicare-b/
23. Crocker A. Medicare Changes in 2024: What Providers Need to Know. *OneOp Readiness Knowledge Network Health and Well Being Newsletter,* 2024.
24. Eaves ER, Hsu CW, DeBar LL, et al. Whole Systems Within Whole Systems: The Oregon Health Plan's Expansion of Services for Back and Neck Pain. *J Altern Complement Med.* 2019;25(S1):S61-s68.
25. Von Korff M, Scher AI, Helmick C, et al. United States National Pain Strategy for Population Research: Concepts, Definitions, and Pilot Data. *J Pain.* 2016;17(10):1068-1080.
26. Humphreys K, Shover CL, Andrews CM, et al. Responding to the opioid crisis in North America and beyond: recommendations of the Stanford-Lancet Commission. *Lancet.* 2022;399(10324):555-604.
27. Interagency Pain Research Coordinating Committee. *National Pain Strategy: A Comprehensive Population Health-Level Strategy by Pain.* 2015 2015.
28. Seal K, Becker W, Tighe J, Li Y, Rife T. Managing Chronic Pain in Primary Care: It Really Does Take a Village. *J Gen Intern Med.* 2017;32(8):931-934.
29. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep 2016.* 2016;65(RR-1):1–49.
30. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med.* 2007;147(7):492-504.
31. Urits I, Schwartz RH, Orhurhu V, et al. A Comprehensive Review of Alternative Therapies for the Management of Chronic Pain Patients: Acupuncture, Tai Chi, Osteopathic Manipulative Medicine, and Chiropractic Care. *Adv Ther.* 2021;38(1):76-89.
32. Rubinstein SM, de Zoete A, van Middelkoop M, Assendelft WJJ, de Boer MR, van Tulder MW. Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomised controlled trials. *Bmj.* 2019;364:l689.
33. Huang JF, Zheng XQ, Chen D, et al. Can Acupuncture Improve Chronic Spinal Pain? A Systematic Review and Meta-Analysis. *Global Spine J.* 2021;11(8):1248-1265.
34. Williams ACC, Fisher E, Hearn L, Eccleston C. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev.* 2020;8(8):Cd007407.
35. Shea CM. A conceptual model to guide research on the activities and effects of innovation champions. *Implement Res Pract.* 2021;2.
36. Bonawitz K, Wetmore M, Heisler M, et al. Champions in context: which attributes matter for change efforts in healthcare? *Implement Sci.* 2020;15(1):62.
37. Fortney JC, Curran GM, Lyon AR, Check DK, Flum DR. Similarities and Differences Between Pragmatic Trials and Hybrid Effectiveness-Implementation Trials. *J Gen Intern Med.* 2024;39(9):1735-1743.
38. Haley AD, Powell BJ, Walsh-Bailey C, et al. Strengthening methods for tracking adaptations and modifications to implementation strategies. *BMC Med Res Methodol.* 2021;21(1):133.
39. Miller CJ, Barnett ML, Baumann AA, Gutner CA, Wiltsey-Stirman S. The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare. *Implement Sci.* 2021;16(1):36.
40. Miech EJ, Rattray NA, Flanagan ME, Damschroder L, Schmid AA, Damush TM. Inside help: An integrative review of champions in healthcare-related implementation. *SAGE Open Med.* 2018;6:2050312118773261.
41. Bunce AE, Gruß I, Davis JV, et al. Lessons learned about the effective operationalization of champions as an implementation strategy: results from a qualitative process evaluation of a pragmatic trial. *Implement Sci.* 2020;15(1):87.
42. Gold R, Bunce A, Davis JV, et al. "I didn't know you could do that": A Pilot Assessment of EHR Optimization Training. *ACI open.* 2021;5(1):e27-e35.
43. Jeyakumar T, McClure S, Lowe M, et al. An Education Framework for Effective Implementation of a Health Information System: Scoping Review. *J Med Internet Res.* 2021;23(2):e24691.
44. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci.* 2015;10:21.
45. Powell BJ, McMillen JC, Proctor EK, et al. A compilation of strategies for implementing clinical innovations in health and mental health. *Med Care Res Rev.* 2012;69(2):123-157.

46. OCHIN. *OCHIN Annual Report: 2023.* OCHIN;2024.
47. Gold R, Middendorf M, Heintzman J, et al. Challenges involved in establishing a web-based clinical decision support tool in community health centers. *Healthc (Amst).* 2020;8(4):100488.
48. Gold R, Sheppler C, Hessler D, et al. Using Electronic Health Record-Based Clinical Decision Support to Provide Social Risk-Informed Care in Community Health Centers: Protocol for the Design and Assessment of a Clinical Decision Support Tool. *JMIR Res Protoc.* 2021;10(10):e31733.
49. Gold R, Larson AE, Sperl-Hillen JM, et al. Effect of Clinical Decision Support at Community Health Centers on the Risk of Cardiovascular Disease: A Cluster Randomized Clinical Trial. *JAMA Netw Open.* 2022;5(2):e2146519.
50. Gold R, Bunce A, Cottrell E, et al. Study protocol: a pragmatic, stepped-wedge trial of tailored support for implementing social determinants of health documentation/action in community health centers, with realist evaluation. *Implement Sci.* 2019;14(1):9.
51. Gunn R, Pisciotta M, Gold R, et al. Partner-developed electronic health record tools to facilitate social risk-informed care planning. *J Am Med Inform Assoc.* 2023;30(5):869-877.
52. Huguet N, Ezekiel-Herrera D, Gunn R, et al. Uptake of a Cervical Cancer Clinical Decision Support Tool: A Mixed-Methods Study. *Appl Clin Inform.* 2023;14(3):594-599.
53. Gunn R, Pisciotta M, Volk M, Bowen M, Gold R, Mossman N. Implementation of Social Isolation Screening and an Integrated Community Resource Referral Platform. *J Am Board Fam Med.* 2023;36(5):803-816.
54. Gunn R, Watkins SL, Boston D, et al. Evaluation of a Remote Patient Monitoring Program During the COVID-19 Pandemic: Retrospective Case Study With a Mixed Methods Explanatory Sequential Design. *JMIR Form Res.* 2024;8:e55732.
55. DeBar L, Mayhew M, Benes L, et al. A Primary Care-Based Cognitive Behavioral Therapy Intervention for Long-Term Opioid Users With Chronic Pain : A Randomized Pragmatic Trial. *Ann Intern Med.* 2022;175(1):46-55.
56. Smith DH, O'Keeffe-Rosetti M, Leo MC, et al. Economic Evaluation: A Randomized Pragmatic Trial of a Primary Care-based Cognitive Behavioral Intervention for Adults Receiving Long-term Opioids for Chronic Pain. *Med Care.* 2022;60(6):423-431.
57. Mayhew M, Balderson BH, Cook AJ, et al. Comparing the clinical and cost-effectiveness of remote (telehealth and online) cognitive behavioral therapy-based treatments for high-impact chronic pain relative to usual care: study protocol for the RESOLVE multisite randomized control trial. *Trials.* 2023;24(1):196.
58. DeBar LL, Bushey MA, Kroenke K, et al. A patient-centered nurse-supported primary care-based collaborative care program to treat opioid use disorder and depression: Design and protocol for the MI-CARE randomized controlled trial. *Contemp Clin Trials.* 2023;127:107124.
59. DeBar LL, Justice M, Avins AL, et al. Acupuncture for chronic low back pain in older adults: Design and protocol for the BackInAction pragmatic clinical trial. *Contemp Clin Trials.* 2023;128:107166.
60. Von Korff M, DeBar LL, Krebs EE, Kerns RD, Deyo RA, Keefe FJ. Graded chronic pain scale revised: mild, bothersome, and high-impact chronic pain. *Pain.* 2020;161(3):651-661.
61. Cherkin DC, Sherman KJ, Balderson BH, et al. Comparison of complementary and alternative medicine with conventional mind-body therapies for chronic back pain: protocol for the Mind-body Approaches to Pain (MAP) randomized controlled trial. *Trials.* 2014;15:211.
62. Cherkin DC, Sherman KJ, Balderson BH, et al. Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain: A Randomized Clinical Trial. *Jama.* 2016;315(12):1240-1249.
63. Cherkin D, Balderson B, Wellman R, et al. Effect of Low Back Pain Risk-Stratification Strategy on Patient Outcomes and Care Processes: the MATCH Randomized Trial in Primary Care. *J Gen Intern Med.* 2018;33(8):1324-1336.
64. Green BB, Anderson ML, Cook AJ, et al. Clinic, Home, and Kiosk Blood Pressure Measurements for Diagnosing Hypertension: a Randomized Diagnostic Study. *J Gen Intern Med.* 2022;37(12):2948-2956.
65. Green BB, Anderson ML, Cook AJ, et al. Financial Incentives to Increase Colorectal Cancer Screening Uptake and Decrease Disparities: A Randomized Clinical Trial. *JAMA Netw Open.* 2019;2(7):e196570.
66. Green BB, Anderson ML, Cook AJ, et al. A Centralized Program with Stepped Support Increases Adherence to Colorectal Cancer Screening Over 9 Years: a Randomized Trial. *J Gen Intern Med.* 2022;37(5):1073-1080.

67. Cook AJ, Delong E, Murray DM, Vollmer WM, Heagerty PJ. Statistical lessons learned for designing cluster randomized pragmatic clinical trials from the NIH Health Care Systems Collaboratory Biostatistics and Design Core. *Clin Trials.* 2016;13(5):504-512.
68. Shortreed SM, Rutter CM, Cook AJ, Simon GE. Improving pragmatic clinical trial design using real-world data. *Clin Trials.* 2019;16(3):273-282.
69. Wang X, Turner EL, Li F, et al. Two weights make a wrong: Cluster randomized trials with variable cluster sizes and heterogeneous treatment effects. *Contemp Clin Trials.* 2022;114:106702.
70. Williamson BD, Coley RY, Hsu C, McCracken CE, Cook AJ. Considerations for Subgroup Analyses in Cluster-Randomized Trials Based on Aggregated Individual-Level Predictors. *Prev Sci.* 2024;25(Suppl 3):421-432.
71. Herman PM, Luoto JE, Kommareddi M, Sorbero ME, Coulter ID. Patient Willingness to Pay for Reductions in Chronic Low Back Pain and Chronic Neck Pain. *J Pain.* 2019;20(11):1317-1327.
72. Herman PM, Lavelle TA, Sorbero ME, Hurwitz EL, Coulter ID. Are Nonpharmacologic Interventions for Chronic Low Back Pain More Cost Effective Than Usual Care? Proof of Concept Results From a Markov Model. *Spine (Phila Pa 1976).* 2019;44(20):1456-1464.
73. Herman PM, Yuan AH, Cefalu MS, et al. The use of complementary and integrative health approaches for chronic musculoskeletal pain in younger US Veterans: An economic evaluation. *PLoS One.* 2019;14(6):e0217831.
74. Herman PM, Broten N, Lavelle TA, Sorbero ME, Coulter ID. Health Care Costs and Opioid Use Associated With High-impact Chronic Spinal Pain in the United States. *Spine (Phila Pa 1976).* 2019;44(16):1154-1161.
75. Herman PM, Whitley MD, Ryan GW, Hurwitz EL, Coulter ID. The impact of patient preferences and costs on the appropriateness of spinal manipulation and mobilization for chronic low back pain and chronic neck pain. *BMC Musculoskelet Disord.* 2019;20(1):519.
76. Herman PM, McBain RK, Broten N, Coulter ID. Update of Markov Model on the Cost-effectiveness of Nonpharmacologic Interventions for Chronic Low Back Pain Compared to Usual Care. *Spine (Phila Pa 1976).* 2020;45(19):1383-1385.
77. Herman PM, Craig BM, Caspi O. Is complementary and alternative medicine (CAM) cost-effective? A systematic review. *BMC Complement Altern Med.* 2005;5:11.
78. Herman PM, Szczurko O, Cooley K, Mills EJ. Cost-effectiveness of naturopathic care for chronic low back pain. *Altern Ther Health Med.* 2008;14(2):32-39.
79. Herman PM, Poindexter BL, Witt CM, Eisenberg DM. Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open.* 2012;2(5).
80. Coulter ID, Herman PM, Nataraj S. Economic analysis of complementary, alternative, and integrative medicine: considerations raised by an expert panel. *BMC Complement Altern Med.* 2013;13:191.
81. Herman PM. Evaluating the economics of complementary and integrative medicine. *Glob Adv Health Med.* 2013;2(2):56-63.
82. Herman PM, Dodds SE, Logue MD, et al. IMPACT--Integrative Medicine PrimAry Care Trial: protocol for a comparative effectiveness study of the clinical and cost outcomes of an integrative primary care clinic model. *BMC Complement Altern Med.* 2014;14:132.
83. Herman PM, Anderson ML, Sherman KJ, Balderson BH, Turner JA, Cherkin DC. Cost-effectiveness of Mindfulness-based Stress Reduction Versus Cognitive Behavioral Therapy or Usual Care Among Adults With Chronic Low Back Pain. *Spine (Phila Pa 1976).* 2017;42(20):1511-1520.
84. Gold R, Bunce AE, Cohen DJ, et al. Reporting on the Strategies Needed to Implement Proven Interventions: An Example From a "Real-World" Cross-Setting Implementation Study. *Mayo Clin Proc.* 2016;91(8):1074-1083.
85. Gold R, Bunce A, Cowburn S, et al. Cardiovascular care guideline implementation in community health centers in Oregon: a mixed-methods analysis of real-world barriers and challenges. *BMC Health Serv Res.* 2017;17(1):253.
86. Gold R, Muench J, Hill C, et al. Collaborative development of a randomized study to adapt a diabetes quality improvement initiative for federally qualified health centers. *J Health Care Poor Underserved.* 2012;23(3 Suppl):236-246.
87. Gold R, Hollombe C, Bunce A, et al. Study protocol for "Study of Practices Enabling Implementation and Adaptation in the Safety Net (SPREAD-NET)": a pragmatic trial comparing implementation strategies. *Implement Sci.* 2015;10:144.

88. Gold R, Bunce A, Cowburn S, et al. Does increased implementation support improve community clinics' guideline-concordant care? Results of a mixed methods, pragmatic comparative effectiveness trial. *Implement Sci.* 2019;14(1):100.
89. Gruß I, Bunce A, Davis J, Gold R. Unintended consequences: a qualitative study exploring the impact of collecting implementation process data with phone interviews on implementation activities. *Implement Sci Commun.* 2020;1(1):101.
90. Sperl-Hillen JM, Rossom RC, Kharbanda EO, et al. Priorities Wizard: Multisite Web-Based Primary Care Clinical Decision Support Improved Chronic Care Outcomes with High Use Rates and High Clinician Satisfaction Rates. *EGEMS (Wash DC).* 2019;7(1):9.
91. Boston D, Larson AE, Sheppler CR, et al. Does Clinical Decision Support Increase Appropriate Medication Prescribing for Cardiovascular Risk Reduction? *J Am Board Fam Med.* 2023;36(5):777-788.
92. Hauschildt J, Lyon-Scott K, Sheppler CR, et al. Adoption of shared decision-making and clinical decision support for reducing cardiovascular disease risk in community health centers. *JAMIA Open.* 2023;6(1):ooad012.
93. Sheppler CR, Larson AE, Boston D, et al. Pandemic-related practice changes and CVD risk management in community clinics. *Am J Manag Care.* 2024;30(1):43-48.
94. Gold R, Cook N, Dankovchik J, et al. Cardiovascular disease risk management during COVID-19: in-person vs virtual visits. *Am J Manag Care.* 2024;30(1):e11-e18.
95. Gold R, Kaufmann J, Gottlieb LM, et al. Cross-Sectional Associations: Social Risks and Diabetes Care Quality, Outcomes. *Am J Prev Med.* 2022;63(3):392-402.
96. Donovan J, Cottrell EK, Hoopes M, et al. Adjusting for Patient Economic/Access Issues in a Hypertension Quality Measure. *Am J Prev Med.* 2022;63(5):734-742.
97. Aceves B, Gunn R, Pisciotta M, et al. Social Care Recommendations in National Diabetes Treatment Guidelines. *Curr Diab Rep.* 2022;22(10):481-491.
98. Morone NE, Greco CM, Moore CG, et al. A Mind-Body Program for Older Adults With Chronic Low Back Pain: A Randomized Clinical Trial. *JAMA Intern Med.* 2016;176(3):329-337.
99. Morone NE, Greco CM, Rollman BL, et al. The design and methods of the aging successfully with pain study. *Contemp Clin Trials.* 2012;33(2):417-425.
100. Yeh CH, Chien LC, Balaban D, et al. A randomized clinical trial of auricular point acupressure for chronic low back pain: a feasibility study. *Evid Based Complement Alternat Med.* 2013;2013:196978.
101. Staman KL, Check DK, Zatzick D, et al. Intervention delivery for embedded pragmatic clinical trials: Development of a tool to measure complexity. *Contemp Clin Trials.* 2023;126:107105.
102. Lane E, Magel JS, Thackeray A, et al. Effectiveness of training physical therapists in pain neuroscience education for patients with chronic spine pain: a cluster-randomized trial. *Pain.* 2022;163(5):852-860.
103. Fritz JM, Lane E, McFadden M, et al. Physical Therapy Referral From Primary Care for Acute Back Pain With Sciatica : A Randomized Controlled Trial. *Ann Intern Med.* 2021;174(1):8-17.
104. Skolasky RL, Wegener ST, Aaron RV, et al. The OPTIMIZE study: protocol of a pragmatic sequential multiple assessment randomized trial of nonpharmacologic treatment for chronic, nonspecific low back pain. *BMC Musculoskelet Disord.* 2020;21(1):293.
105. Fritz JM, Rhon DI, Teyhen DS, et al. A Sequential Multiple-Assignment Randomized Trial (SMART) for Stepped Care Management of Low Back Pain in the Military Health System: A Trial Protocol. *Pain Med.* 2020;21(Suppl 2):S73-s82.
106. Schoville RR, Titler MG. Guiding healthcare technology implementation: a new integrated technology implementation model. *Comput Inform Nurs.* 2015;33(3):99-107; quiz E101.
107. Schoville R, Titler MG. Integrated Technology Implementation Model: Examination and Enhancements. *Comput Inform Nurs.* 2020;38(11):579-589.
108. Schoville RR. Discovery of Implementation Factors That Lead to Technology Adoption in Long-Term Care. *J Gerontol Nurs.* 2017;43(10):21-26.
109. Groeneveld SWM, den Ouden MEM, van Gemert-Pijnen J, Verdaasdonk RM, van Os-Medendorp H. Underestimated Factors Regarding the Use of Technology in Daily Practice of Long-Term Care: Qualitative Study Among Health Care Professionals. *JMIR Nurs.* 2023;6:e41032.
110. McCleary NJ, Merle JL, Richardson JE, et al. Bridging clinical informatics and implementation science to improve cancer symptom management in ambulatory oncology practices: experiences from the IMPACT consortium. *JAMIA Open.* 2024;7(3):ooae081.
111. Owens-Jasey C, Chen J, Xu R, et al. Implementation of Health IT for Cancer Screening in US Primary Care: Scoping Review. *JMIR Cancer.* 2024;10:e49002.

112. Göttgens I, Oertelt-Prigione S. The Application of Human-Centered Design Approaches in Health Research and Innovation: A Narrative Review of Current Practices. *JMIR Mhealth Uhealth.* 2021;9(12):e28102.
113. Cooley M. *Human-centered Systems.* London: Springer; 1989.
114. Matheson GO, Pacione C, Shultz RK, Klügl M. Leveraging human-centered design in chronic disease prevention. *Am J Prev Med.* 2015;48(4):472-479.
115. Danitz SB, Stirman SW, Grillo AR, et al. When user-centered design meets implementation science: integrating provider perspectives in the development of an intimate partner violence intervention for women treated in the United States' largest integrated healthcare system. *BMC Womens Health.* 2019;19(1):145.
116. Dopp AR, Parisi KE, Munson SA, Lyon AR. Aligning implementation and user-centered design strategies to enhance the impact of health services: results from a concept mapping study. *Implement Sci Commun.* 2020;1:17.
117. Vindrola-Padros C, Johnson GA. Rapid Techniques in Qualitative Research: A Critical Review of the Literature. *Qual Health Res.* 2020;30(10):1596-1604.
118. Nevedal AL, Reardon CM, Opra Widerquist MA, et al. Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). *Implement Sci.* 2021;16(1):67.
119. Waltz TJ, Powell BJ, Matthieu MM, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. *Implement Sci.* 2015;10:109.
120. Willis G. *Cognitive interviewing; A tool for improving questionnaire design.* Sage; 2005.
121. Meadows K. Cognitive Interviewing Methodologies. *Clin Nurs Res.* 2021;30(4):375-379.
122. Li F, Turner EL, Heagerty PJ, Murray DM, Vollmer WM, DeLong ER. An evaluation of constrained randomization for the design and analysis of group-randomized trials with binary outcomes. *Stat Med.* 2017;36(24):3791-3806.
123. Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. *J Gen Intern Med.* 2009;24(6):733-738.
124. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain.* 2005;113(1-2):9-19.
125. Kroenke K, Evans E, Weitlauf S, et al. Comprehensive vs. Assisted Management of Mood and Pain Symptoms (CAMMPS) trial: Study design and sample characteristics. *Contemporary clinical trials.* 2018;64:179-187.
126. Dworkin RH, Turk DC, McDermott MP, et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain.* 2009;146(3):238-244.
127. Zou G. A modified poisson regression approach to prospective studies with binary data. *Am J Epidemiol.* 2004;159(7):702-706.
128. Li P, Redden DT. Small sample performance of bias-corrected sandwich estimators for cluster-randomized trials with binary outcomes. *Stat Med.* 2015;34(2):281-296.
129. Powell BJ, Fernandez ME, Williams NJ, et al. Enhancing the Impact of Implementation Strategies in Healthcare: A Research Agenda. *Front Public Health.* 2019;7:3.
130. Wang ML, Jacobs O. From Awareness to Action: Pathways to Equity in Pain Management. *Health Equity.* 2023;7(1):416-418.

Data Management and Sharing Plan
Our study team is committed to transparency and reproducibility of all research processes and products to support real-world decision making around replicability of interventions in real-world settings.

Element 1: Data Type:

A. Types and amount of scientific data expected to be generated in the project:
The CARNATION study will generate qualitative data on experience with the implementation strategies /intervention and opportunities for improvement; this information will be collected from advisory group meetings and co-development workshops, qualitative interviews with community health center (CHC) staff and patients, as well as meeting observations with CHC teams.

CARNATION will also utilize data from patient electronic health records (EHR) in standardized formats, including the data related to pain management care coordination that is entered by CHC staff into the EHR-integrated Compass Rose module. However, all clinical data that will be used in this study are existing within patient charts and not collected as part of this study. There will be no consenting of individual patients receiving integrated pain management-related services supported by the study implementation support, as the clinical assessment and pain-related services patents are part of standard care at the CHCs.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
All qualitative data and EHR-based datasets produced during the project will be preserved on secure OCHIN servers. All OCHIN data is hosted in a HIPAA Audited tier III data center. All data work will be conducted on secure, password-protected HIPAA compliant OCHIN computers. OCHIN computers are protected through the use of passwords and encryption (Microsoft Bitlocker for whole disk encryption) as well as other industry standard controls such as password strength, password expiration, screen lockout, password obfuscation, defense in-depth (multiple firewalls), IPS/IDS, DLP and centralized audit and event logging of all platforms to a central SIEM platform for all services following HIPAA/NIST 800-53 controls.

The analytic EHR-based datasets produced by OCHIN will be transferred to the KPWHRI analytic team (Dr. Andrea Cook and Mr. Robert Wellman, biostatisticians) who will conduct the quantitative primary, secondary and exploratory analyses. In addition, an analytic dataset will also be provided/transferred to RAND where Dr. Patricia Herman will conduct the cost analyses.

Patient-level datasets, qualitative data, and Epic/Clarity electronic health record (EHR) code and variable names will not be shared. As described above, all clinical data that will be used in this study are existing within patient charts and not collected as part of this study; patient consent will not be obtained for use of these EHR data. The OCHIN Research Data Warehouse (RDW) includes patient-level data generated from multiple health systems across the OCHIN network; restrictions apply to the availability and re- release of patient-level data under organizational member agreements. Therefore, to honor member agreements and protect potentially identifiable patient information, patient-level datasets, qualitative data, and Epic/Clarity code and variables names cannot be shared publicly. Epic/Clarity variable names will be removed and replaced before sharing statistical data analytic code (e.g., R, SAS). The study team discussed this inability to comply with the HEAL Data Sharing Requirements with the Scientific/Research Contacts for **RFA-NS-24-041** during an October 2, 2024 conference call.

Aggregate data, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will be shared with relevant publications or by the end of the project period. OCHIN defines aggregate data as a dataset or data display that consolidates data from multiple individuals (e.g., patients) and does not contain identifiers that can be used to identify individual patients.

C. Metadata, other relevant data, and associated documentation:
To facilitate interpretation of aggregate data to be shared, documentation (i.e., data dictionary), qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will also be shared.

Element 2: Related Tools, Software and/or Code:
OCHIN uses SQL to access EHR data stored in a Research Data Warehouse (RDW). Qualitative data will be entered into QSR NVivo for data analysis.

Data will be analyzed by the KPWHRI analytic team per the CARNATION study protocol and statistical analysis plan using R.

Element 3: Standards:
All OCHIN researchers and staff are trained in and follow federal HIPAA regulations, which require specific protocols for the transferring, storage, and reporting of protected health information (PHI). In addition, OCHIN requires all Research personnel to complete CITI training in the Responsible Conduct of Research. OCHIN computers are protected through the use of passwords and encryption (Microsoft Bitlocker for whole disk encryption) as well as other industry standard controls such as password strength, password expiration, screen lockout, password obfuscation, defense in-depth (multiple firewalls), IPS/IDS, DLP and centralized audit and event logging of all platforms to a central SIEM platform for all services following HIPAA/NIST 800-53 controls. All OCHIN data is hosted in a HIPAA Audited tier III data center.

Element 4: Data Preservation, Access and Associated Timelines:

A. Repository where scientific data and metadata will be archived:

All scientific data that can be shared will be deposited as supplementary material with manuscripts in PubMed Central or another suitable public repository. Other scientific data generated in this project that cannot be publicly shared will be preserved for five (5) years and then archived on secure OCHIN servers as described above indefinitely.

B. How scientific data will be findable and identifiable:

Aggregate data will be included as supplementary material with manuscripts on PubMed Central, thus the metadata and persistent identifiers (i.e., PMCID) will be supported by the National Library of Medicine. Each PubMed Central study is also assigned a digital object identifier (DOI) to facilitate findability of scientific data.

C. When and how long the scientific data will be made available:

The research community will have access to aggregate data, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) as soon as possible or at the time of associated publication, but no later than the end of the project period. Shared scientific data and associated qualitative codebooks, statistical data analytic code (e.g., R, SAS), and data dictionaries will be available indefinitely and access will not be controlled by the study team or OCHIN.

Qualitative data: Audio recordings of interviews and online meeting recordings (e.g., Zoom) will be securely stored and professionally transcribed by an outside vendor (who OCHIN has a Business Associates Agreement with). Recordings will be sent via secure file transfer (SFT) to be transcribed; access to the SFT site will be limited to appropriate members of the research team. Any identifiable patient information (inadvertently shared by clinic staff) in the transcript will be deleted. The transcriptionist will send back the file to the appropriate members of the research team via SFT. Recordings, transcripts, and digital copies of all collected artifacts will be kept on a secure network at OCHIN and accessible to qualitative team members. The study team will keep an audit trail for all qualitative data and enter data into QSR NVivo for data analysis. Qualitative data will not be shared publicly; however, codebooks will be shared as described above.

EHR data: OCHIN EHR data is centrally maintained. No transfer needs to occur from the CHC to OCHIN research analysts. Clinical data and research data (once abstracted) are stored on and backed up on secure servers and all data work will be conducted on secure, password-protected HIPAA compliant OCHIN computers. Facilities that store PHI in paper or electronic form have controlled access procedures and 24 hour monitored alarm service. Patient-level datasets containing EHR data will not be shared publicly; however, aggregate data will be shared as described above.

Element 5: Access, Distribution, or Reuse Considerations:

CARNATION will be registered on ClinicalTrials.gov and the CARNATION protocol and study findings will be shared in peer-reviewed journals per journal policies.

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

As described above, patient-level datasets, qualitative data, and Epic/Clarity electronic health record (EHR) code and variable names cannot be shared. All clinical data to be used in this study are existing within patient charts and not collected as part of this study; patient consent will not be obtained for use of these EHR data.

The OCHIN Research Data Warehouse includes patient-level electronic health record (EHR) data generated from multiple health systems across the OCHIN network; restrictions apply to the availability and re- release of patient-level data under organizational member agreements. Therefore, to honor member agreements and protect potentially identifiable patient information, patient-level datasets, qualitative data, and Epic/Clarity code and variables names cannot be shared publicly. Epic/Clarity variable names will be removed and replaced before sharing statistical data analytic code (e.g., R, SAS).

B. Whether access to scientific data will be controlled:

Manual of Procedures: The KP CHR and OCHIN Research Associates will collaboratively develop a study replication plan that will include the Institutional Review Board (IRB)-approved study protocol, approvals, data documentation (e.g., data dictionary), analysis plans, and research products. As the study progresses, this plan will be updated and made available to interested researchers.

Access to aggregate scientific data and data dictionaries, qualitative codebooks, and statistical data analytic code (e.g., R, SAS) will not be controlled. Other scientific data generated as part of the project (e.g., patient-level datasets, qualitative data) will not be shared even if requested to uphold OCHIN member and vendor agreements and patient and study participant confidentiality.

Types of Research Products: We will share products resulting from this research which have been specified as sharable with publications or by the end of the project period. Products will include study process flows, non-proprietary assessment tools (e.g., interview guide), the study replication plan, and actionable recommendations developed during the mixed-method analysis. We will not be able to share our patient-level research datasets maintained by OCHIN, as these data were collected for clinical purposes, and it is not allowed to be shared per data use agreements with OCHIN member clinics.

We developed the following plan for dissemination of study materials and findings to primary care and safety-net organizations, including Community Health Centers, and academic colleagues through a variety of methods. While conducting this study and disseminating findings, we will use community engagement strategies with OCHIN member clinics as active partners. The content of materials disseminated through presentations and, and manuscripts will be driven by study findings.

Presentations: Study results will be shared through presentations at international, national, and local conferences and forums, including peer-reviewed conferences with large public health and health center representation.

Manuscripts: The research project team will present findings through peer-reviewed manuscripts and commentaries.

C. Protections for privacy, rights, and confidentiality of human research participants:

Once patient-level data are pulled from the Research Data Warehouse, direct identifiers will be immediately removed by Research Analysts before providing to the research team for analysis to protect human subjects' privacy, rights, and confidentiality. Thus, all identifying information will be removed prior to sharing aggregate scientific data. All OCHIN researchers and staff are trained in and follow federal HIPAA regulations, which require specific protocols for the transferring, storage, and reporting of protected health information (PHI). In

addition, OCHIN requires all personnel contributing to the design and/or conduct of this research to complete CITI training in the Responsible Conduct of Research.

For the proposed qualitative data collection from human research participants, IRB-approved informed consent documents will include language describing plans for data management and sharing, motivation for sharing data, and explain that any potentially identifying information will be removed. We will not share transcripts, even with identifiers removed, but will share qualitative codebooks publicly.

Element 6: Oversight of Data Management and Sharing:

The OCHIN Research Department is responsible for overseeing implementation and compliance with this plan, specifically the OCHIN Principal Investigator, Dr. Rachel Gold.