

**National Institutes of Health • Department of Defense • Department of Veterans Affairs
Pain Management Collaboratory:
Updates, lessons learned, and future directions**



Robert D. Kerns, Ph.D. on behalf of the Pain Management Collaboratory

Spotlight on Pain Management

October 3, 2023

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- Its contents are solely the responsibility of the author and does not necessarily represent the official views of the NCCIH, OBSSR, and the National Institutes of Health, and the Departments of Defense and Veterans Affairs and the US government.

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This presentation is a product of the **NIH-DOD-VA Pain Management Collaboratory**.

[https://painmanagementcollaboratory.org/.](https://painmanagementcollaboratory.org/)

NIH-DOD-VA Pain Management Collaboratory

Approximately \$81 Million investment over six years

Sponsors:

NIH

- National Center for Complementary and Integrative Health, National Institute for Neurological Disorders and Stroke, National Institute of Drug Abuse, National Institute of Alcohol Abuse and Alcoholism, National Institute of Child Health and Human Development, National Institute of Nursing Research, Office of Behavioral and Social Sciences Research, Office of Research on Women's Health



DOD

- Clinical Rehabilitative Medicine Research Program, Military Operational Medicine Research Program

VA

- Health Services Research & Development Service, Office of Research and Development

Gap between evidence and practice

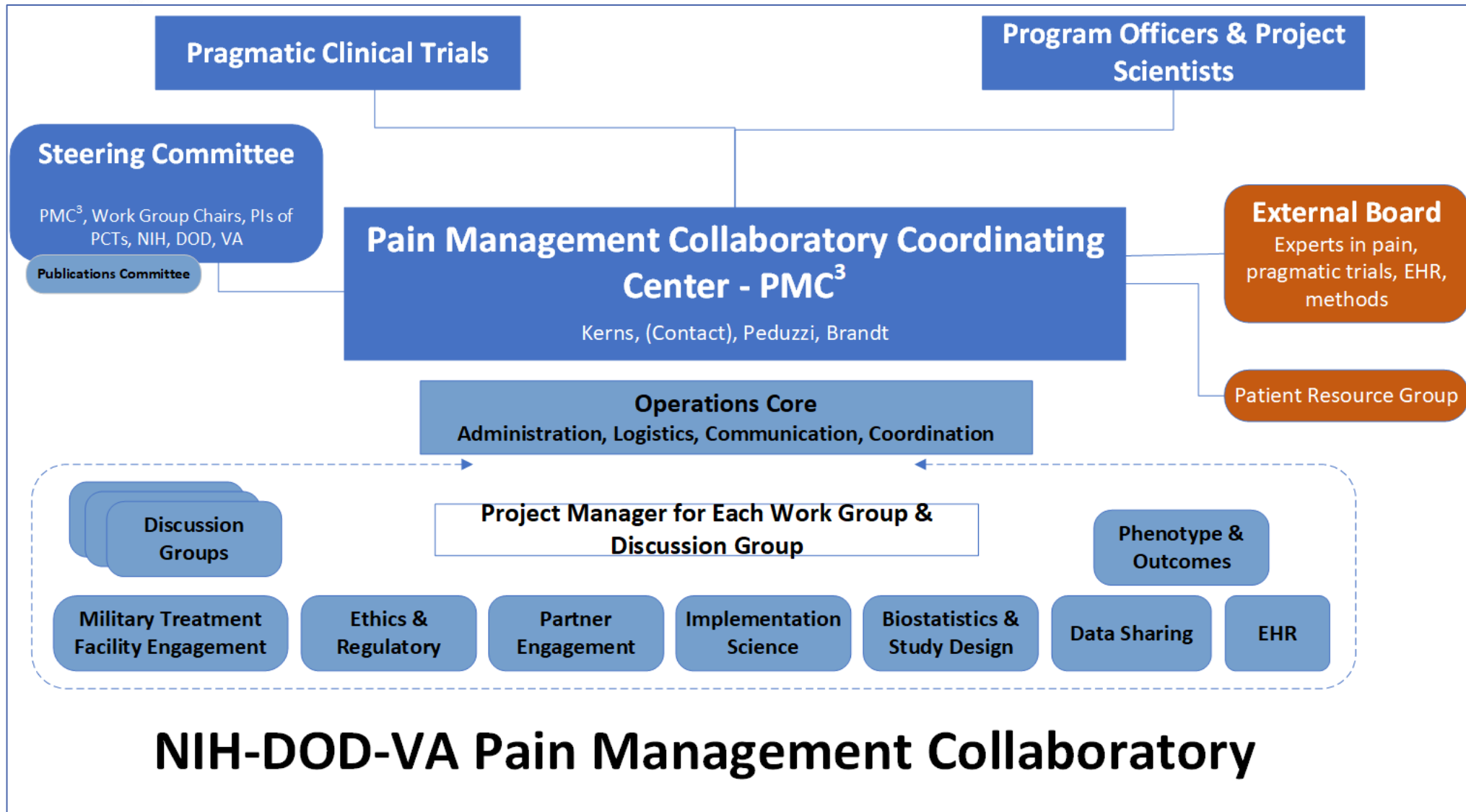
- Growing evidence to support integrated, coordinated, multimodal and interdisciplinary models of pain care that support patient activation and pain self-management
- 
- Significant organizational/systems, provider and patient-level barriers to timely and equitable access to these approaches
- 
- Veteran and military health systems are ideally positioned to address this gap



NIH-DOD-VA Pain Management Collaboratory

Key Objective

- Conduct pragmatic clinical trials to evaluate whether nonpharmacological approaches for management of pain and common co-occurring conditions and integrated models of care are effective when delivered in the Veteran Health Administration (VHA) and/or the Defense Health Agency (DHA)
- Why pragmatic studies?
 - Emphasize generalizability of results and protect rigor
 - Answer questions that inform VHA and DHA about what services to make available to patients with pain throughout their systems
 - Results may inform other health care systems about nonpharmacological treatments for pain management





Pragmatic Clinical Trials

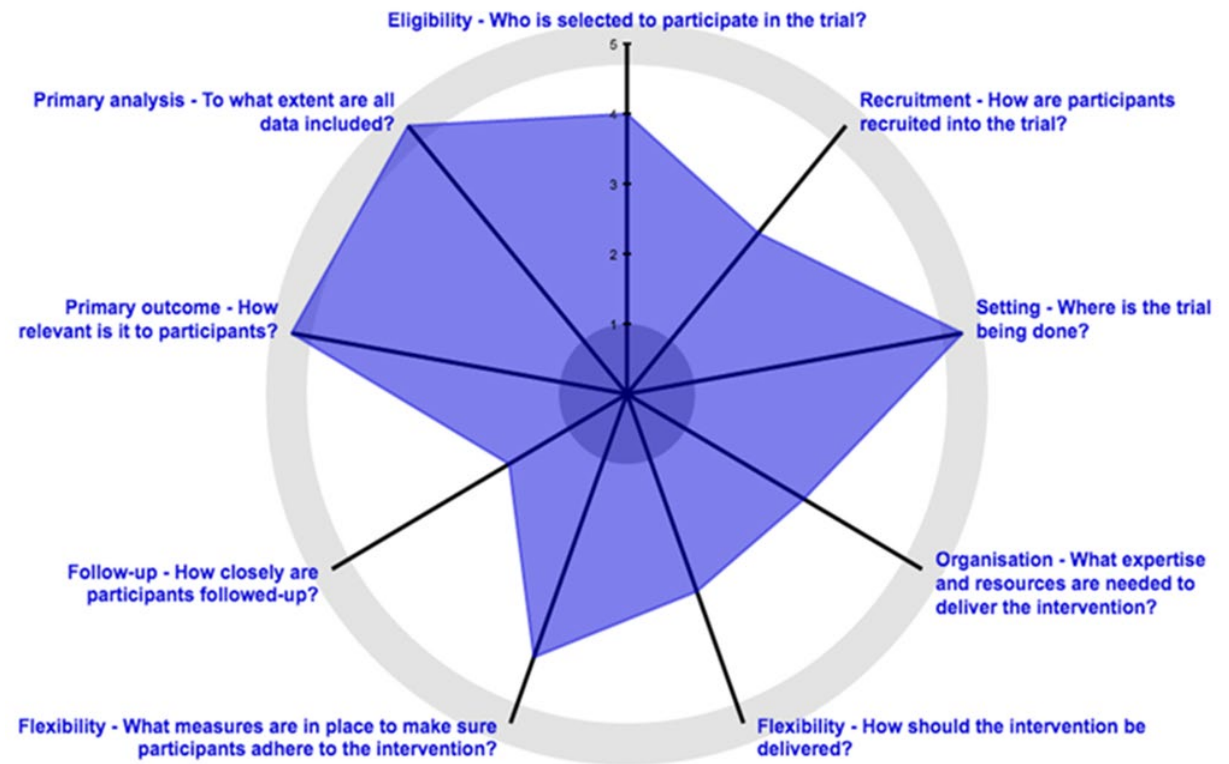
- Phased cooperative agreement research applications to conduct large-scale, pragmatic clinical trials
 - 1-2 year planning phase
 - 4 year implementation phase
 - Transition to the implementation phase dependent upon completing milestones in the planning phase
 - During the implementation phase, the Pragmatic Clinical Trial teams worked with their respective funding agency and the PMC Coordinating Center to coordinate resource needs and monitor progress

PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) Domains

- Eligibility: Minimal exclusion criteria (e.g., persons with significant alcohol use/abuse included)
 - Recruitment: In the flow of routine clinical care
 - Setting: Clinical care settings (e.g., primary care, PT, surgery)
 - Organization: Limited additional resources or training (e.g., clinical staff deliver interventions)
 - Flexibility (in intervention delivery): Patient-centered; flexible; adaptations consistent with optimized clinical care (e.g., COVID related adaptations)
 - Flexibility (in intervention receipt/adherence): Minimal enhancements beyond those embedded in the interventions
 - Follow-up: Consistent with routine clinical follow-up
 - Primary outcomes: Patient-centered (i.e., pain and pain reduction, ability to function in daily life, quality of life, and medication usage/reduction/discontinuation)
 - Primary analyses: Intent to treat approach
- Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015 May 8;350:h2147. doi: 10.1136/bmj.h2147. PMID: 25956159.

Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP (Long and Goertz)

1. Evaluate the comparative effectiveness of a low dose (1-5 visits) of standard chiropractic care against a higher dose (8-12 visits) in Veterans with cLBP.
2. Evaluate the comparative effectiveness of chiropractic chronic pain management (CCPM; one scheduled chiropractic visit per month x 10 months), compared to usual care, following the initial treatment described in Aim 1.
3. Evaluate the impact of CCPM on health services outcomes compared to usual care.
4. Evaluate patient and clinician perceptions of non-specific treatment factors, effectiveness of study interventions, and impact of the varying doses of standard chiropractic care and the CCPM on clinical outcomes across 3 VA facilities using a mixed method, process evaluation approach.



13 Pragmatic Clinical Trials

J. Fritz/D. Rhon:

SMART Stepped Care Management for Low Back Pain in Military Health System (NIH)

A. Heapy/D. Higgins:

Cooperative Pain Education and Self-management: Expanding Treatment for Real-world Access (COPEs ExTRA) (NIH)

K. Seal/W. Becker:

Implementation of a Pragmatic Trial of Whole Health Team vs. Primary Care Group Education to Promote Non-Pharmacological Strategies to Improve Pain, Functioning, & Quality of Life in Veterans (NIH)

S. Taylor/S. Zeliadt:

Complementary and Integrative Health for Pain in the VA: A National Demonstration Project (VA)

C. Goertz/C. Long:

Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP (NIH)

M. Rosen/S. Martino:

Engaging Veterans Seeking Service-Connection Payments in Pain Treatment (NIH)

S. George/S.N. Hastings:

Improving Veteran Access To Integrated Management of Chronic Back Pain (AIM-BACK) (NIH)

B. Ilfeld:

Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacological Alternative for the Treatment of Postoperative Pain (DOD)

D. McGeary/J. Goodie:

Targeting Chronic Pain in Primary Care Settings Using Internal Behavioral Health Consultants (DOD)

T. Lovejoy/B. Morasco

Tele-Collaborative Outreach to Rural Patients with Chronic Pain: The CORPs Trial (NIH)

M. Rosen/S. Martino

Implementation Facilitation of Screening, Brief Intervention, and Referral to Treatment for Pain Management for Veterans Separating from Military Service (NIH)

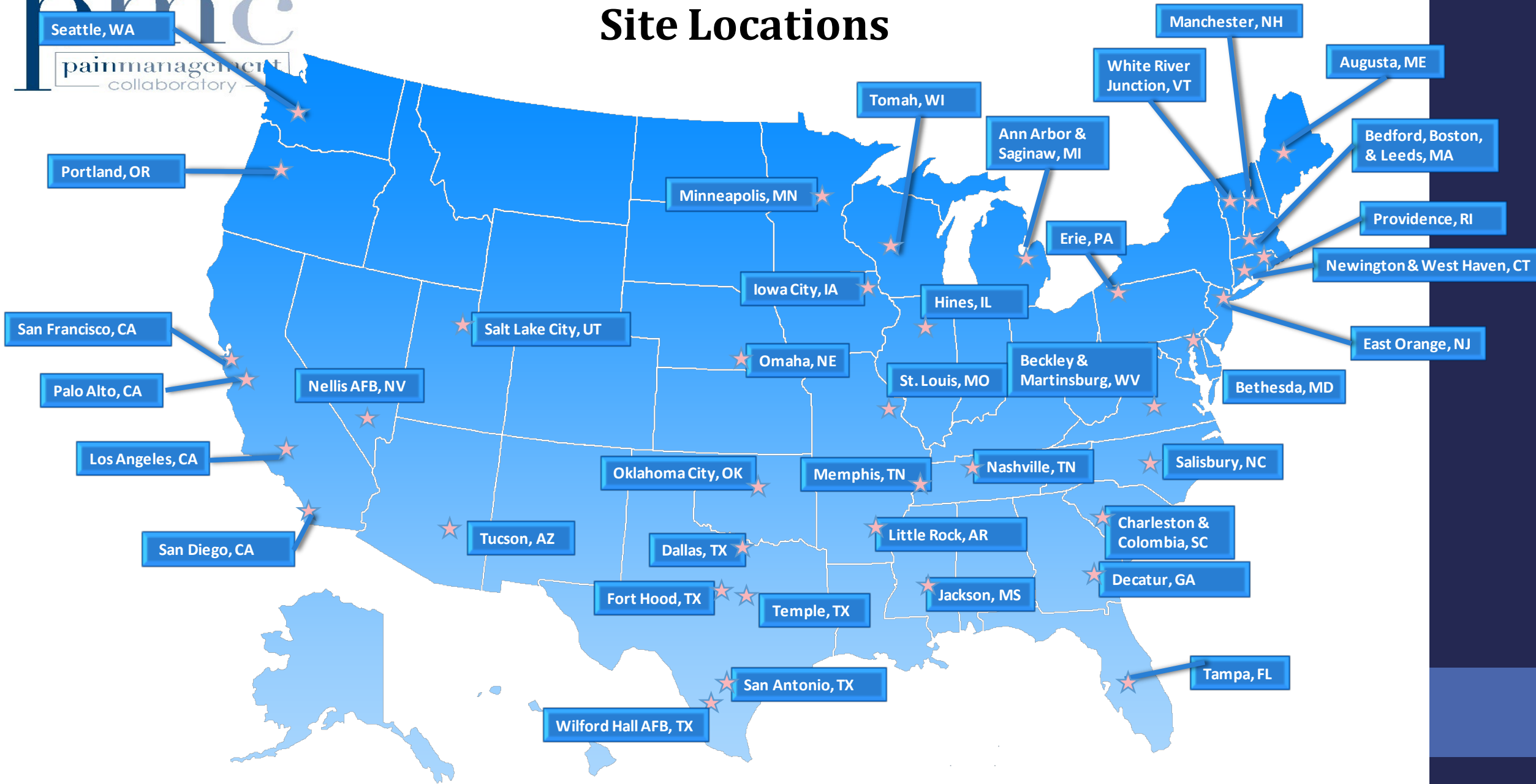
C. Dearth/B. Hendershot:

Resolving the Burden of Low Back Pain in Military Service Members and Veterans (RESOLVE Trial) (DOD)

D. Burgess:

Learning to Apply Mindfulness to Pain (LAMP) (DOD)

Site Locations





Enrollment Update

(As of September 2023)

Race/Ethnicity	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported			Total
	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown	
American Indian or Alaskan Native	16	38	0	8	15	0	7	30	12	126
Asian	33	107	1	1	3	0	69	122	17	353
Native Hawaiian or Pacific Islander	23	60	0	4	15	0	103	84	1	290
Black or African American	684	1402	0	15	51	0	132	272	121	2677
White or Caucasian	1149	4696	0	130	596	0	444	919	438	8372
More than one race	34	93	0	9	21	0	48	87	10	302
Unknown or Not Reported	59	135	0	51	179	0	142	317	16	899
Total	1998	6531	1	218	880	0	945	1831	615	13019

Barriers Score Card across 12 trials

(as of September 2023)

Barriers	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects	3	2	2	4	0
Engagement of clinicians and Health Systems	2	5	1	3	0
Data collection and merging datasets	4	6	1	0	0
Regulatory issues (IRBs and consent)	9	2	0	0	1
Stability of control intervention	4	4	2	1	0
Implementation/Delivering Intervention Across Healthcare Organizations	1	5	1	4	0

Project Milestones

- All projects (except Rosen/Martino-2) have transitioned to implementation phase

Biostatistics advice

- Project specific consultation
- Missing Data, ICC and Covariates addressed with “White papers” developed
- Modification to statistical analysis plans (e.g., impact of COVID)
- Current focus: Adherence and Fidelity Monitoring

Site Overlap

- A two-step process was implemented to address site overlap to optimize recruitment of diverse samples: (1) information-gathering phase and (2) mediation phase to develop plans to address overlap.
- Remediation efforts focused on exclusion criteria and recruitment strategies.

Geda, M., George, S.Z., Burgess, D.J., Scarton, D.V., Roddy, W.T., Gordon, K.S., Pasquina, P.F., Brandt, C.A., Kerns, R. D., Peduzzi, P. and on behalf of the NIH-DoD-VA Pain Management Collaboratory (2020). Strategy for addressing research-site overlap in pragmatic clinical trials: lessons learned from the NIH-DOD-VA Pain Management Collaboratory (PMC). *Trials*, 20, 1021.

Treatment Fidelity

- **Ensuring the integrity of the independent variable**
- **Balancing pragmatism/flexibility and fidelity of treatment delivery and receipt (adherence)**
- Gordon, K., Peduzzi, P. & Kerns, R.D. (2020). Designing trials with purpose: Pragmatic clinical trials of nonpharmacological approaches for pain management. *Pain Medicine, 21 (Supplement 2), S7-S12.*
- Kerns, R.D., Davis, A.F., Fritz, J.M., Keefe, F.J., Peduzzi, P., Rhon, D.I., Taylor, S. L., Vining, R., Yu, Q., Zeliadt, S.B. & George, S.Z. (2023), Intervention fidelity in pain pragmatic trials for nonpharmacologic pain management: Nuanced considerations for determining PRECIS-2 flexibility in delivery and adherence. *Journal of Pain, 24, 568-574.*

Optimizing recruitment

Site selection

- Addressed overlapping sites
- Explicit attention to geography, race/ethnicity, and rural/urban settings
- In VA, accessed the Practice Based Research Network
- Engaged existing network of pain scientists at potential recruitment sites

Sampling and recruitment approaches

- Embedded trials rely on routine patient care pathways
- Proactive recruitment
 - Use of the electronic health record to identify potential candidates
 - Second tier screening and consenting
 - Development and implementation of alerts for clinicians/staff
 - Tailored recruitment materials to target underrepresented groups
- Active engagement of Patient Resource Group and other similar entities within VA

Explicit attention to justice and equity

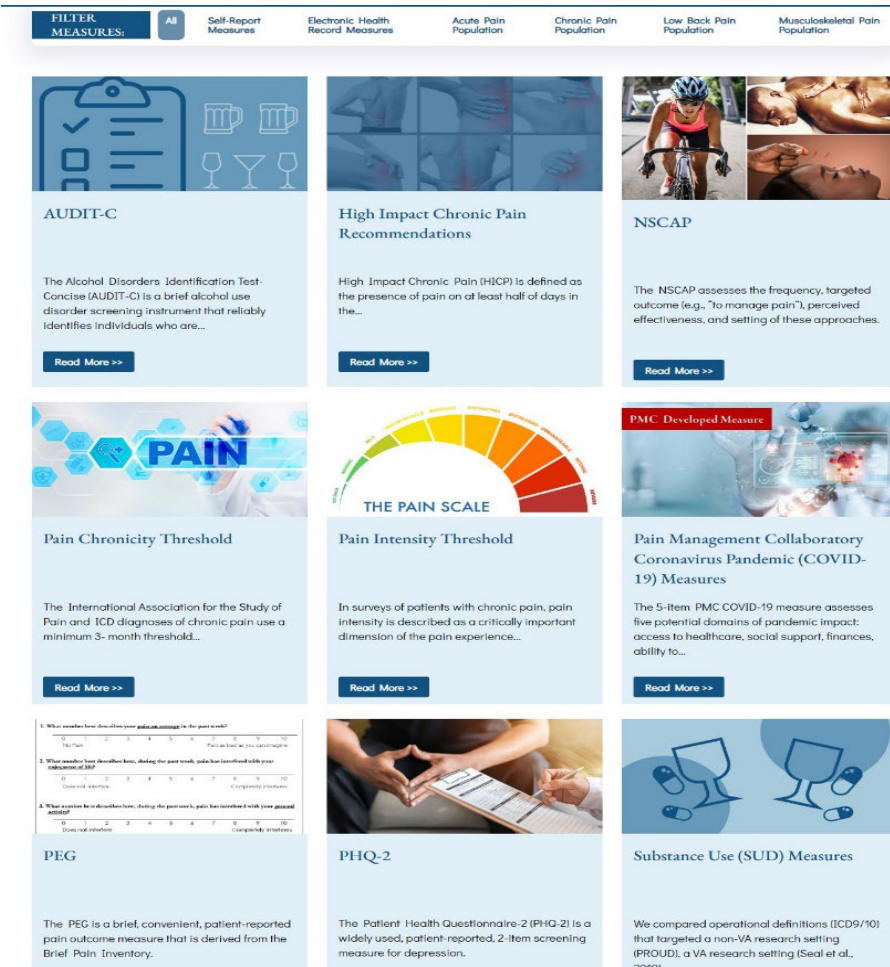
Ali, J., Davis, A., Burgess, D., Rhon, D., Vining, R., Young-McCaughan, S., Green, S. & Kerns, R.D. (2021). Justice and equity in pragmatic clinical trials: Considerations for pain research in integrated health systems. *Learning Health Systems*, 6, e10291.

Ethical and Regulatory Challenges and Opportunities

- Shared learning and identification of best practices
 - Continue to address multiple ongoing challenges regarding IRB, privacy, data security and other regulatory hurdles
 - Ongoing dialogue with IRB representatives
 - Inconsistencies across IRBs
 - Need for education regarding pragmatic clinical trials
 - Involvement of clinical staff (e.g., ethical duty to participate?, clinicians as research staff, thus requiring additional training and certification?)
- Toolkit in development
- Addressing coincidental or collateral findings
- Focus on justice and equity
 - Recruitment of representative samples
 - Optimizing plans for dissemination to diverse communities

Phenotypes & Outcomes Work Group Data Harmonization

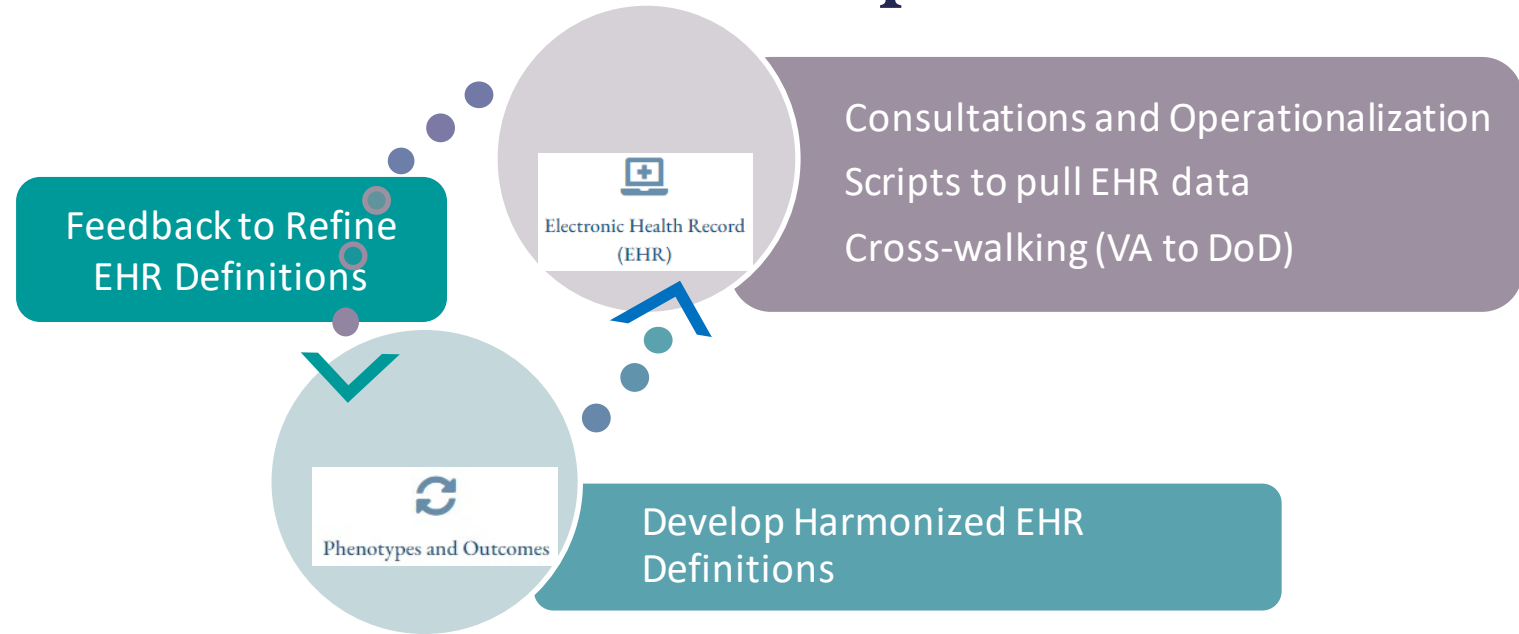
1. Eligibility Criteria
 - a. Pain Chronicity & Severity Thresholds
2. Baseline Characteristics
 - a. Alcohol Use (AUDIT-C)
 - b. Depression (PHQ-2)
 - c. High Impact Chronic Pain (HICP)
 - d. Table 1 Baseline Characteristics
3. Outcomes
 - a. Pain Intensity and Interference (PEG-3)
 - b. Healthcare Utilization
4. Other Outcome and Covariate Measurements
 - a. Opioid Use
 - b. Substance Use Disorder (SUD)
 - c. Nonpharmacological Pain Treatments/
Complementary Integrative Health (NPT/CIH)
Survey
 - d. Coronavirus/COVID-19 Survey



The screenshot displays a website interface for the Pain Management Collaboratory. At the top, there is a navigation bar with tabs for 'FILTER MEASURES', 'All', 'Self-Report Measures', 'Electronic Health Record Measures', 'Acute Pain Population', 'Chronic Pain Population', 'Low Back Pain Population', and 'Musculoskeletal Pain Population'. Below this, the page is organized into a grid of nine content cards, each representing a different measure or threshold:

- AUDIT-C:** The Alcohol Disorders Identification Test-Concise (AUDIT-C) is a brief alcohol use disorder screening instrument that reliably identifies individuals who are...
- High Impact Chronic Pain Recommendations:** High Impact Chronic Pain (HICP) is defined as the presence of pain on at least half of days in the...
- NSCAP:** The NSCAP assesses the frequency, targeted outcome (e.g., "to manage pain"), perceived effectiveness, and setting of these approaches.
- Pain Chronicity Threshold:** The International Association for the Study of Pain and ICD diagnoses of chronic pain use a minimum 3-month threshold...
- THE PAIN SCALE:** In surveys of patients with chronic pain, pain intensity is described as a critically important dimension of the pain experience...
- PMc Developed Measure:** Pain Management Collaboratory Coronavirus Pandemic (COVID-19) Measures. The 5-item PMC COVID-19 measure assesses five potential domains of pandemic impact: access to healthcare, social support, finances, ability to...
- PEG:** The PEG is a brief, convenient, patient-reported pain outcome measure that is derived from the Brief Pain Inventory.
- PHQ-2:** The Patient Health Questionnaire-2 (PHQ-2) is a widely used, patient-reported, 2-item screening measure for depression.
- Substance Use (SUD) Measures:** We compared operational definitions (ICD9/10) that targeted a non-VA research setting (PROUD), a VA research setting (Seal et al., 2011).

P&O and EHR Work Group Collaboration



- **P&O WG-** developed standardized **EHR Definition for Healthcare Utilization** using VA stop codes (in consultation with EHR Co-Chairs).
- **EHR WG-** Developed a **cross-walk** from VA stop codes used in Healthcare Utilization to MDR codes supporting **harmonization across VA and DOD sites**.

Coleman BC, Goulet JL, Higgins DM, Bathulapalli H, Kawecky T, Ruser CB, Bastian LA, Martino S, Piette JD, Edmond SN, Heapy AA. ICD-10 Coding of musculoskeletal conditions in the Veterans Health Administration. Pain Medicine 2021;22(11):2597-2603.

Optimizing partner engagement

- Patient Resource Group
- External Board
- VHA Joint Clinical and Research Leadership Group
- Emergence of a similar effort with DHA colleagues and entities
- Spotlight on Pain Management
- Potential Joint Incentive Fund initiatives
- NIH Pragmatic Trials Collaboratory

Bastian, L.A., Cohen, S.P., Katsovich, L., Becker, W.C., Brummett, B.R., Burgess, D.J., Crunkhorn, A.E., Denneson, L.E., Frank, J.W., Goertz, C., Ilfeld, B., Kanzler, K.E., Krishnaswamy, A., LaChappelle, K., Martino, S., Mattocks, K., McGeary, C.A., Reznik, T.E., Rhon, D.I., Salsbury, S.A., Seal, K.H., Semiatin, A.M., Shin, M.H., Simon, C.B., Teyhen, D.S., Zamora, K. & Kerns R.D. (2020). **Stakeholder engagement in pragmatic clinical trials: Emphasizing relationships to improve pain management delivery and outcomes.** *Pain Medicine, 21 (Supplement 2), S13-S20.*

Anicich, A., Katsovich, L. & Kerns, R.D. (2022). **Engaging veterans and military service members to optimize pragmatic clinical trials of nonpharmacological approaches for pain management.** *Pain Medicine, 23, 1201-1204.*

Implementation Science WG

PMC Website: Guidance for Study Design and Proposals

Guidance for Study Design & Proposals

A selection of publications, tools, and recommendations for developing strong proposals and adaptive studies

Publications

Writing implementation research grant proposals: Ten key ingredients

Enola K. Proctor, Byron J. Powell, Ana A. Baumann, Ashley M. Hamilton and Ryan L. Santens
Implementation Science
October 12, 2012

Acknowledging the challenges and nuances of crafting stand-out study proposals that address implementation, the Proctor, et al., recommend important elements for research scientists to include in their grant applications. The authors identify 10 key ingredients that make an application stronger and convey the significance and impact of the proposed study to reviewers.

[Learn about the 10 key ingredients for making stronger grant proposals.](#)

Analysis of “learn-as-you-go” (LAGO) studies

Daniel Nevo, Judith J. Lok, Donna Spiegelman
The Annals of Statistics
2021, Vol. 49, No. 2, 793–819

What are ways that investigators can plan to apply in stages during a study, and a design and Multiphase Optimization Strategy

Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD, Brian Mittman, PhD, Jeffrey M. Pyne, MD, and Cheryl Steller, PhD
Med Care
March 2012

The authors examine how hybrid study designs can address the gaps in the translation of health care research to health care practice and health care promotion. The study proposed three approaches and assessed their potential for further consideration in speeding the transition and translation from research studies to health care practices and education.

[Read the full article on Pub Med.](#)

Increasing the impact of randomized controlled trials: an example of a hybrid effectiveness-implementation design in psychotherapy research

Adrienne L. Johnson, Anthony H. Ecker, Terri L. Fletcher, Natalie Hundt, Michael R. Kauth, Lindsey A. Martin, Geoffrey M. Curran, Jeffrey A. Cully
Translational Behavioral Medicine
November 26, 2018

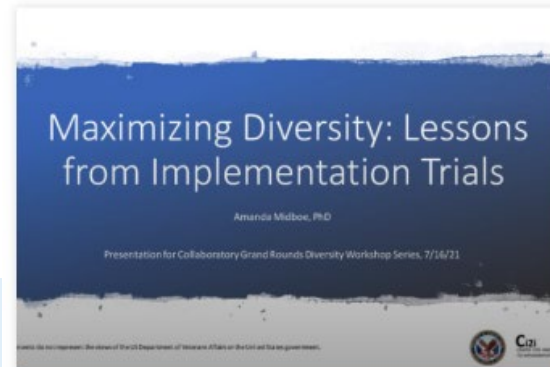
Randomized Controlled Trials (RCT) have been the go-to for clinical studies; however, the long delays from research to dissemination to health care practice bring about considerations for implementations in study design. The authors conclude that expanding “traditional” RCTs through collaborative stakeholder contributions and stakeholder/consumer-informed implementation approaches is critical to improve adoption post project.”

[Read Full Paper in Translational Behavioral Medicine](#)

Making sense of implementation theories, models and frameworks

Per Nilsen
Implementation Science
April 21, 2015

Presentations



Maximizing Diversity: Lessons from Implementation Trials

The intent of this presentation is to highlight lessons from implementation trials that can be applied to increase diversity, equity, and inclusion in future trials. There is a focus on stakeholder engagement early and often as well as a reminder to define what diversity means for your particular implementation trial.

[READ MORE >](#)



Challenges and Opportunities to Integrate Evidence-Based Complementary Interventions into Traditional Healthcare Settings

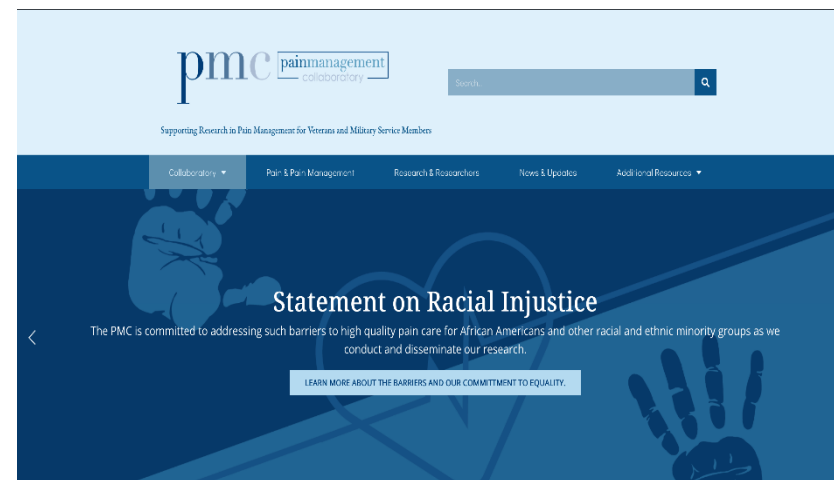
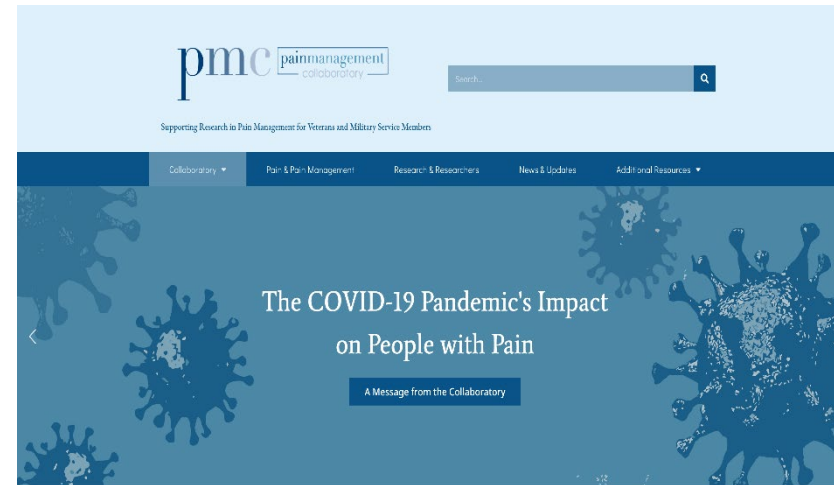
This presentation outlines some key pieces that are necessary for implementation science grants, including methods and design considerations that are relevant to implementation science.

[READ MORE >](#)

Responses to recent events affecting people with pain

Developed written response to COVID-19 pandemic on PMC website and coordinated and supported unified measures to account for COVID-19 impact across all PCTs.

Crafted written and video responses to “Black Lives Matter” and disparities in pain care, leveraging PMC PCT PI expertise.



Response to COVID 19

- Built a supportive community, drawing on the strengths of the PMC, VA and DOD as learning healthcare systems.
- Coordinated effort to identify significant changes to PCT protocols (sampling and recruitment plans, assessments, interventions) as a function of COVID.
- Developed survey instrument to assess impact of COVID for study participants.
- Collaborated with NIH Health Systems Research Collaboratory to identify solutions and best practices, and to develop recommendations for appropriate analytic approaches to address protocol adaptations.
- Encouraged ongoing communication between PCT PIs and sponsoring agency program officers and relevant IRBs and DSMBs regarding potential protocol changes.

Addressing COVID Impacts

- Coleman, B.C et al, on behalf of the NIH-DoD-VA Pain Management Collaboratory, (2020). **Adapting to disruption of research during the COVID-19 pandemic while testing nonpharmacological approaches to pain management.** *Translational Behavioral Medicine*, 10, 827–834.
- Fritz, J.M., et al. (2021). **Pivoting to virtual delivery for managing chronic pain with nonpharmacological treatments – Implications for pragmatic research.** *Pain*, 162, 1591-1596.
- Coleman, B.C. et al. (2021). **Assessing the impact of the COVID-19 pandemic on pragmatic clinical trial participants,** *Contemporary Clinical Trials*, 111, 106619.
- Lazar CM, et al.(2022). **Counseling veterans with chronic pain during the COVID-19 pandemic: a secondary analysis of a randomized controlled trial.** *Pain Medicine*, 23, 1434-1441.
- Roytman, G. et al. (2021). **Changes in the use of telehealth and face-to-face chiropractic care in the Department of Veterans Affairs before and after the COVID-19 Pandemic,** *Journal of Manipulative and Physiological Therapy*, 44, 584-590.
- Kerns, R.D. et al. (2022). **Chronic pain self-management: Psychologically-guided core competencies for providers.** *Pain Medicine*, 23, 1815-1819.
- Rhon, D.L. et al. (2022), **Precision in reporting of virtual health interventions used in clinical trials -adapting the template for the intervention description and replication (TIDieR) checklist.** *BMC Medical Research Methodology*, 22, 161.
- Midboe, A. et al. (2023). **Impact of COVID-19 pandemic on nonpharmacological pain management trials in military and veteran healthcare settings: an evaluation informed by implementation science,** *Translational Behavioral Medicine*, 13, 601–611,

Publication by Implementation Science Work Group (2023)

Midboe AM, et al., 2023. doi.org/10.1093/tbm/ibad015

- **Purpose:**
 - a) To describe modifications to PCTs and interventions to address the evolving pandemic
 - b) To describe the application of implementation science methods for evaluation of those PCT modifications.
- **Methods:** two-phase, sequential, mixed-methods design.
 - Phase I: PCT disruptions and modifications via a REDCap questionnaire, using Periodic Reflections methods as a guide.
 - Phase II: Framework for Reporting Adaptations and Modifications-Expanded (FRAME) taxonomy to develop a focus group interview guide and checklist that would provide more in-depth data than Phase I.
- **Results:**
 - Key goals for modifying interventions: increasing treatment feasibility and decreasing patient exposure to COVID-19, while preserving intervention core elements.
 - All eleven PCTs made between two to six trial modifications.
 - Context (format) modifications: eight out of eleven PCTs modified parts of the interventions for virtual delivery.
 - Content modifications:
 - Added elements to enhance patient safety;
 - Tailored interventions for virtual delivery (counseling, exercise, mindfulness);
 - Modified interventions involving manual therapies.

Pathways for Managing Low Back Pain

The Collaborative Efforts of Four PMC PIs Yield a Paper & a Call to Action

INTEGRATING EVIDENCED-BASED THERAPIES INTO THE CLINICAL SETTING

<https://painmanagementcollaboratory.org>

Top pages (January 2023 through August 2023)

1. [Collaboratory Home Page](#)
2. [Pain Management History Timeline](#)
3. [The IASP Revised Definition of Pain](#)
4. [PEG](#)
5. [About NIH-DOD-VA Pain Management Collaboratory](#)
6. [Pain Intensity Threshold](#)
7. [The Six Essential Elements of Good Pain Care](#)
8. [Pragmatic Trials](#)
9. [The Whole Health Model](#)
10. [Pain & Pain Management](#)

Recent Website Additions

Pain Awareness Month Banner
(September 2023)

PMC Publications

CORPS Trial general
information

Patient Resource Group (PRG)
(2023 growth focus)

Website Statistics

Old Stats Collector (Since we started tracking in 2019:

Total Page Views: 40,734

Total Unique Visitors: 18,089

Pages/Visits: 2.25

New Collector (June 10–August 11)

Total Page Views: 10,680

Total Visitors: 1,639

First Time Visitors: 683

Pages/Visits: 6.52

Recent Initiatives

- **Guidelines and best practices for changing statistical analysis plans (SAPs)**
 - When to change SAPs?
 - How to document changes?
 - What is considered a major change in the analytic plan?
- **Approaches for monitoring adverse events in nonpharmacologic pain trials**
 - What is the risk of the population?
 - What events to collect and when?
 - What is the mechanism for independent monitoring of adverse events in real time? DSMB? Safety Officer?
- **Dissemination planning**
 - Worksheet of various strategies for the PMC3 projects to use when they have study results to disseminate
 - Article for publication detailing the strategies for studies to use when considering who to best communicate and disseminate their research findings
- **Implementation planning**
 - Pragmatic trials are in essence hybrid effectiveness-implementation trials in which systematic assessment of factors affecting implementation of innovations being tested in the trials and the development of strategies to improve their use must be considered

Expansion of the Collaboratory

- The PMC3 has developed a rich infrastructure that can be used for additional pain research.
- This initiative will leverage the PMC³ for an additional 6 years including;
 1. The continued support of the Coordinating Center through a limited competition funding opportunity announcement; and
 2. A second set of pragmatic clinical trials which expand PMC scope to new research areas relevant to veterans and service members experiencing pain



Thanks

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