NIH-DoD-VA Pain Management Collaboratory

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Kerns Disclosures

- Research support
  - Department of Veterans Affairs
  - National Institutes of Health
  - Patient-Centered Outcomes Research Institute
  - Consortium of Multiple Sclerosis Centers
- No discussion of unlabeled uses
- This presentation does not reflect official policy or positions of the Departments of Health and Human Services, Defense or Veterans Affairs.

Pain Management is a high priority for the Departments of Health and Human Services (HHS), Defense (DoD) and Veterans Affairs (VA)

- 1998 - VA launched its National Pain Management Strategy
- 2010 - Army Surgeon General's Pain Management Task Force Report published
- 2015 - National Center for Complementary and Integrative Health (NCCIH) Council Working Group Report on "Strengthening collaborations with the DoD and VA" published

NIH-DoD-VA Pain Management Collaboratory Program Press Releases Fall 2017

National Center for Complementary and Integrative Health

NIH...Turning Discovery Into Health

Health Info | Research | Grants & Funding | Training

Federal agencies partner for military and veteran pain management research

Joint HHS-DoD-VA initiative will award multiple grants totaling $81 million

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For Immediate Release:
Wednesday, September 20, 2017

Through an interagency partnership, the U.S. Department of Health and Human Services, the U.S. Department of Defense (DoD), and the U.S. Department of Veterans Affairs (VA) announce a multi-component research project focusing on nondrug approaches for pain management addressing the needs of service members and veterans. Twelve research projects, totaling approximately $81 million over six years (pending available funds), will focus on developing, implementing, and testing cost-effective, large-scale, real-world research on nondrug approaches for pain management and related conditions in military and veteran health care delivery organizations. The National Institutes of Health (NIH) will be the lead HHS agency in this partnership.

"Finding solutions for chronic pain is of critical importance, especially for military personnel and veterans who are disproportionately affected," said NIH Director Francis S. Collins, M.D., Ph.D. "Bringing the science to bear through these real-world research projects will accelerate our search for pain management strategies for all Americans, especially as we work to address the nation's opioid crisis."

View infograph

[NIH Press Release]

U.S. Department of Veterans Affairs

VA SITE MAP [A-Z]

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VA » Health Care » HSR&D » News » Research_news » VA Joins NIH and DoD to Announce Pain Management Research Partnership

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Research News

VA Joins NIH and DoD to Announce Pain Management Research Partnership

November 8, 2017

Through an interagency partnership, the National Institutes of Health and Department of Defense, and Department Veterans Affairs announce a research collaboration focusing on non-drug approaches for pain management addressing the needs of service members and military Veterans.

Twelve research projects totaling approximately $81 million over six years will focus on developing, implementing, and testing cost-effective, large-scale, real-world research on non-drug approaches for pain management and relate conditions in military and Veteran health care organizations. An emphasis of this NIH-led initiative will be on non-dru approaches including mindfulness/meditation interventions, movement interventions (e.g., structured exercise, tai c yoga), manual therapies (e.g., spinal manipulation, massage, acupuncture), psychological and behavioral interventions (e.g., cognitive behavioral therapy), and integrative approaches involving more than one intervention. Specific projects conducted at multiple VA medical centers will focus on low back pain treatment, non-drug self-management for chronic pain, and chiropractic care.

[VA Press Release]

NIH Collaboratory Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

NIH Collaboratory Living Textbook

Est. 2012

- A collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of pragmatic clinical trials.
- Intended to help accelerate change and will continue to be added to and updated.

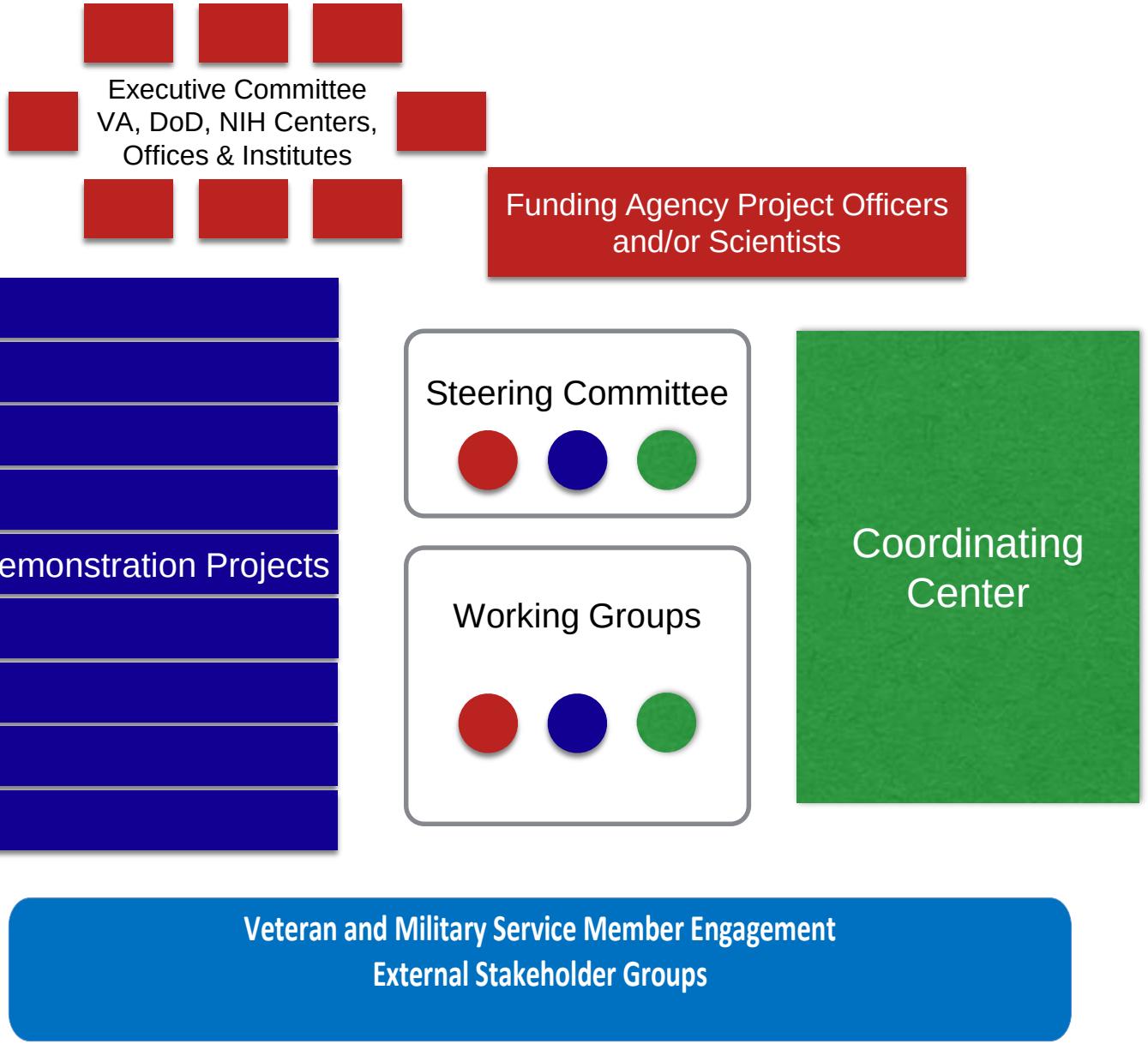
http://rethinkingclinicaltrials.org/

NIH-DoD-VA Pain Management Collaboratory

- Overall Goal: Develop the capacity to implement cost-effective large-scale clinical research in military and veteran health care delivery organizations focusing on non-pharmacological approaches to pain management and other comorbid conditions.
- Sponsors:
  - NIH: NCCIH, NINDS, NIDA, NIAAA, NICHD, NCMRR, ORWH, NINR, OBSSR
  - DoD: Clinical Rehabilitation Medicine Research Program (CRMRP), Military Operational Medicine Research Program (MOMRP)
  - VA: Health Services Research and Development (HSRD)

Objectives of the Collaboratory are:

- Establish a Coordinating Center to provide leadership and technical expertise in all aspects of research supporting the design and execution of high impact demonstration projects on non-pharmacological approaches for pain management and other comorbid conditions;
- Support the design and execution of a set of high-impact Demonstration Projects that will conduct pragmatic clinical trials on non-pharmacological approaches to pain management and comorbidities with patients in health care delivery systems that provide care to military personnel, veterans and their families;
- Make data, tools, best practices, and resources from these and other projects available to facilitate a research partnership with health care delivery systems that provide care to military personnel, veterans and their families


Executive Committee
VA, DoD, NIH Centers, Offices & Institutes
Funding Agency Project Officers and/or Scientists
Demonstration Projects
Steering Committee
Working Groups
Coordinating Center
Veteran and Military Service Member Engagement
External Stakeholder Groups

Pragmatic Clinical Trials Demonstration Projects

- Phased cooperative agreement research applications to conduct efficient, large-scale pragmatic clinical trials Demonstration Projects
- These projects are funded as phased awards with a 2 year planning phase (UG3) and 2-4 year implementation phase (UH3).
- All projects are milestone-driven, and moving to the implementation phase (UH3) will be dependent upon the successful progress made during the planning phase (UG3).
- The Demonstration Projects will generally be performed within large health care systems that utilize electronic health records to leverage data collection that occurs in health care delivery rather than requiring independent research data collection.

Demonstration Project Outcomes

- Primary: pain and pain reduction, ability to function in daily life, quality of life, and medication usage/reduction/discontinuation
- Secondary: assessing comorbid conditions or those co-occurring with high frequency in this population

Demonstration Projects

1. J. Fritz/D. Rhon: SMART Stepped Care Management for Low Back Pain in Military Health System (NIH)
2. S. George/S.N. Hastings: Improving Veteran Access To Integrated Management of Chronic Back Pain (NIH)
3. C. Goertz/C. Long: Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP (NIH)
4. A. Heapy: Cooperative Pain Education and Self-management: Expanding Treatment for Real-world Access (COPES ExTRA) (NIH)
5. M. Rosen/S. Martino: Engaging Veterans Seeking Service-Connection Payments in Pain Treatment (NIH)
6. 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, and Quality of Life in Veterans (NIH)

Demonstration Projects

7. S. Taylor/S. Zeliadt: Complementary and Integrative Health for Pain in the VA: A National Demonstration Project (VA)
8. D. Burgess: Testing Two Scalable, Veteran-Centric Mindfulness-Based Interventions for Chronic Musculoskeletal Pain: A Pragmatic, Multisite Trial (DoD)
9. S. Farrokhi/C. Dearth: Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A Multi-Site Pragmatic Clinical Trial (RESOLVE Trial) (DoD)
10. B. Ilfeld: Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacological Alternative for the Treatment of Postoperative Pain (DoD)
11. D. McGeary/J. Goodie: Targeting Chronic Pain in Primary Care Settings Using Internal Behavioral Health Consultants (DoD)

Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A Multi-Site Pragmatic Clinical Trial (RESOLVE Trial)

Shawn Farrokhi, PT, PhD
Christopher Dearth, PhD
Elizabeth Russell Esposito, PhD

DoD-VA Extremity Trauma and Amputation Center of Excellence (EACE)

- Grant Number(s): NH170003
- Project Period: May 15, 2018 – May 14, 2024
- Study sponsors: Congressionally Directed Medical Research Programs (CDMRP)

Research Question(s)/Hypotheses

- **Specific Aim 1:** To evaluate the effectiveness of an active clinical practice guidelines (CPG) adherence strategy utilizing an education/audit/feedback model with specific training in psychologically informed physical therapy (PIPT) as compared to usual care (UC) for reducing pain and improving disability in Service Members and Veterans with low back pain (LBP) receiving physical therapy (PT).
  - **Hypothesis 1:** CPG+PIPT will be more effective than UC in reducing pain and improving disability.
- **Specific Aim 2:** To compare the medical resource utilization and analgesic medication use between patients receiving CPG+PIPT and UC at 12 months.
  - **Hypothesis 2:** CPG+PIPT will be more effective at reducing medical resource utilization and analgesic medication use as compared to UC over 12 months.
- **Exploratory Aim 3:** Identify the predictors of clinical benefits from PT care for patients with LBP.
  - **Hypothesis 3:** Baseline patient characteristics such as age, gender, body mass index, lower limb amputation and psychological risk category will predict beneficial clinical outcomes.

Design and Methodology

- Study Design
  - Pragmatic, cluster randomized, controlled trial
- Patient Population
  - **4672** Service Members/Veterans with **LBP**
  - Referred to **Physical Therapy** for treatment
- Recruitment Sites
  - Naval Medical Center San Diego (DoD)
  - Walter Reed National Military Medical Center (DoD)
  - Brooke Army Medical Center (DoD)
  - James A. Haley Hospital in Tampa (VA)
  - Audie L. Murphy Memorial Center in San Antonio (VA)

Design and Methodology

- Randomization
  - Physical therapists will be cluster randomized
  - Block Randomization at **1:1** allocation ratio
  - Stratified by site and expected patient volume

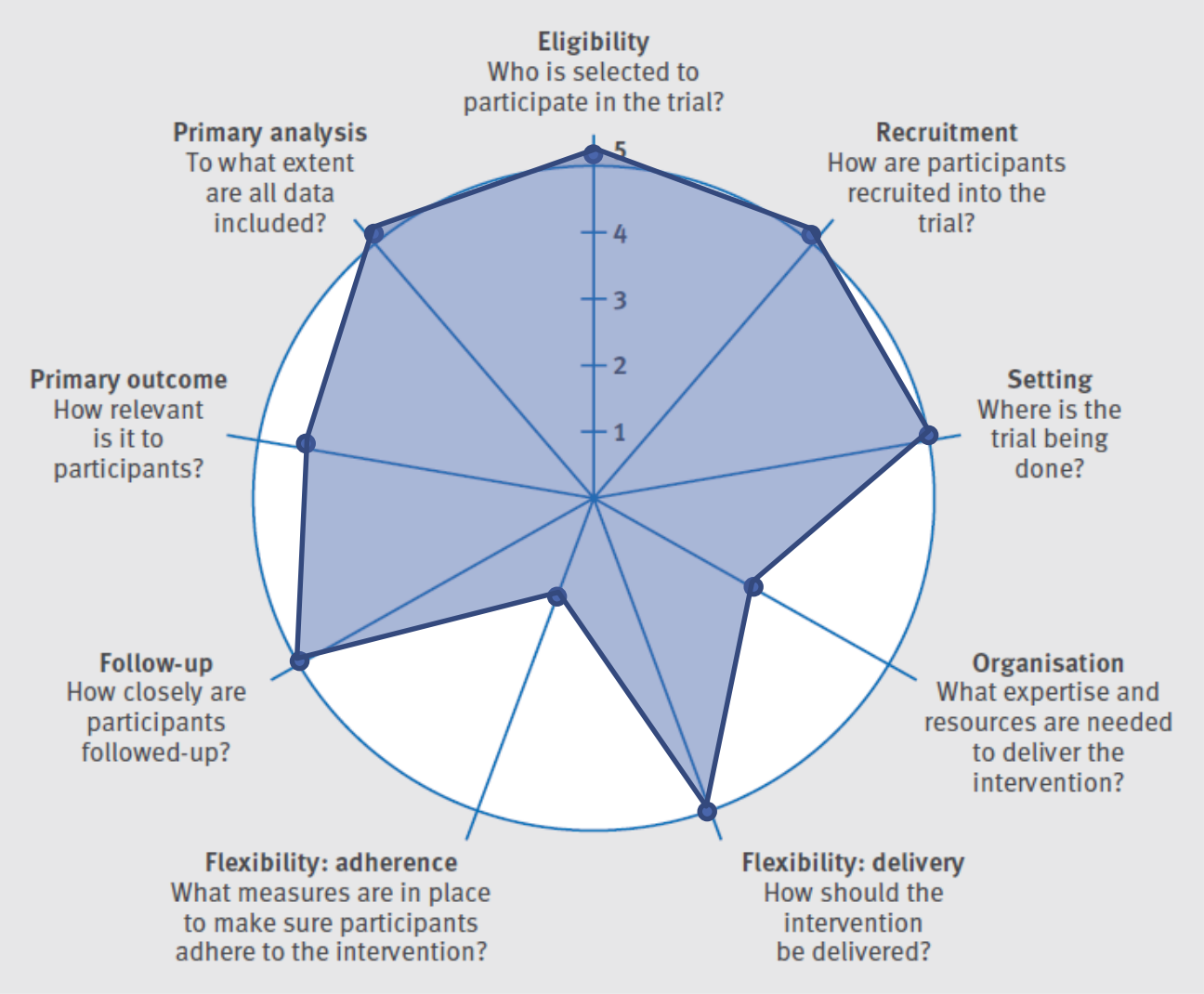
- Interventions
  - Intervention arm
    - Education on PT CPG recommendation by peer opinion leaders
      - **Psychologically Informed Physical Therapy**
    - Monthly audit/feedback
      - CPG adherence rates
      - Patient outcomes
  - Comparator arm (usual care)
    - CPG recommendations provided by standard passive methods
    - Will be instructed to “continue to practice as usual”

Outcomes

- **Oswestry Disability Index (ODI)**
  - The ODI is a condition-specific measure of functional status for patients with LBP, composed of a 10-item, 100-point scale, with higher numbers indicating greater disability.
- **Numeric Pain Rating Scale (NPRS)**
  - The 11-point NPRS is a measure of pain in which patients rate their pain ranging from 0 (no pain) to 10 (worst imaginable pain).
- **LBP-Related Medical Resource Utilization**
  - Referrals to specialists (e.g., orthopedists, spine surgeons, physiatrists, etc.)
  - Tests (e.g., x-rays, MRIs), surgical procedures (e.g., epidural injections, laminectomy).
  - Prescribing patterns for key drug classes commonly used for LBP management such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen (Tylenol), opioid analgesics, skeletal muscle relaxants, antidepressants, and drugs for neuropathic pain (gabapentin).
- **Predictors of Physical Therapy Outcome**
  - Age, height, weight, body mass index, gender, ethnicity, race, lower limb amputation status, education level, socioeconomic status, history of smoking, substance abuse, and LBP chronicity will be recorded to be evaluated as potential predictors of treatment outcome and to describe the sample as required for the NIH Minimum Dataset.
  - The nine-item Subgroups for Targeted Treatment (STarT) Back Screening Tool (SBT) will be used to identify subgroups of patients as high-risk, medium-risk, or low-risk for physical and psychosocial prognostic factors.

Loudon et al. BMJ 2015;350:h2147

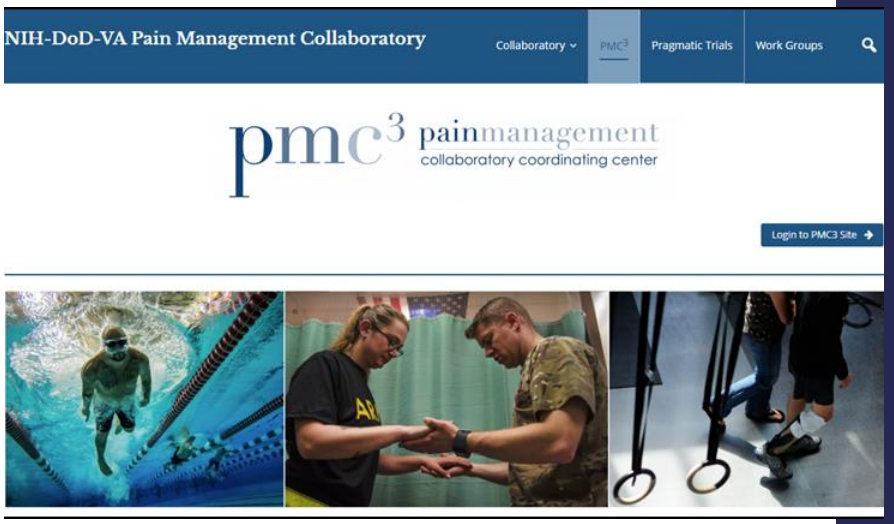
PRECIS Figure for the Study



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

Pain Management Collaboratory Coordinating Center (PMC^3)

Robert Kerns, Cynthia Brandt, and Peter Peduzzi
Yale University and VA Connecticut Healthcare System



- Works with Demonstration Project teams to develop, initiate and implement a research protocol
- Coordinates and convenes Steering Committee of all PIs and federal partner representatives
- Support Demonstration Projects via PMC work groups
- Disseminate best research practices and within military and veteran health care systems

Painmanagementcollaboratory.org

Pain Management Collaboratory Coordinating Center (PMC^3) Specific Aims

- Aim 1. To develop, adapt and adopt technical policy guidelines and best practices for the effective design and conduct of pragmatic trials;
- Aim 2. To work collaboratively with and provide operational, technical, design and other support to Demonstration Project teams to develop, initiate and implement a research protocol; and
- Aim 3. To widely disseminate NIH-DoD-VA Pain Management Collaboratory endorsed policies and best practices and lessons learned within military and veteran health care systems.

pmc
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PMC^3

Pain Research, Informatics, Multimorbidities and Education (PRIME) Center of Innovation

- National leadership in pain research and pain management studies, especially multisite effectiveness trials of non-pharmacological approaches for chronic pain management;
- Expertise in ethics and regulatory compliance
- Expertise in engagement of key VA stakeholders, clinicians and Veterans;
- Expertise on pain phenotyping and outcomes using EHR
- Expertise in electronic health record (EHR) informatics research

Center for Rehabilitation Sciences Research (CRSR)

- National leadership in research on pain, trauma and comorbidities among military service members and families
- Expertise in conduct of trials in military treatment facilities
- Ethical and regulatory compliance in DoD and DoD EHRs
- Expertise in engagement of key DoD stakeholders
- Headquartered at the Uniformed Services University of the Health Sciences (USU)

VA Cooperative Studies Program (CSP) / Clinical Epidemiology Research Center (CERC)

- Multicenter data coordination for VA and DoD
- International Organization for Standardization (ISO) Certification
- Phenotyping, comorbidity assessment, observational studies

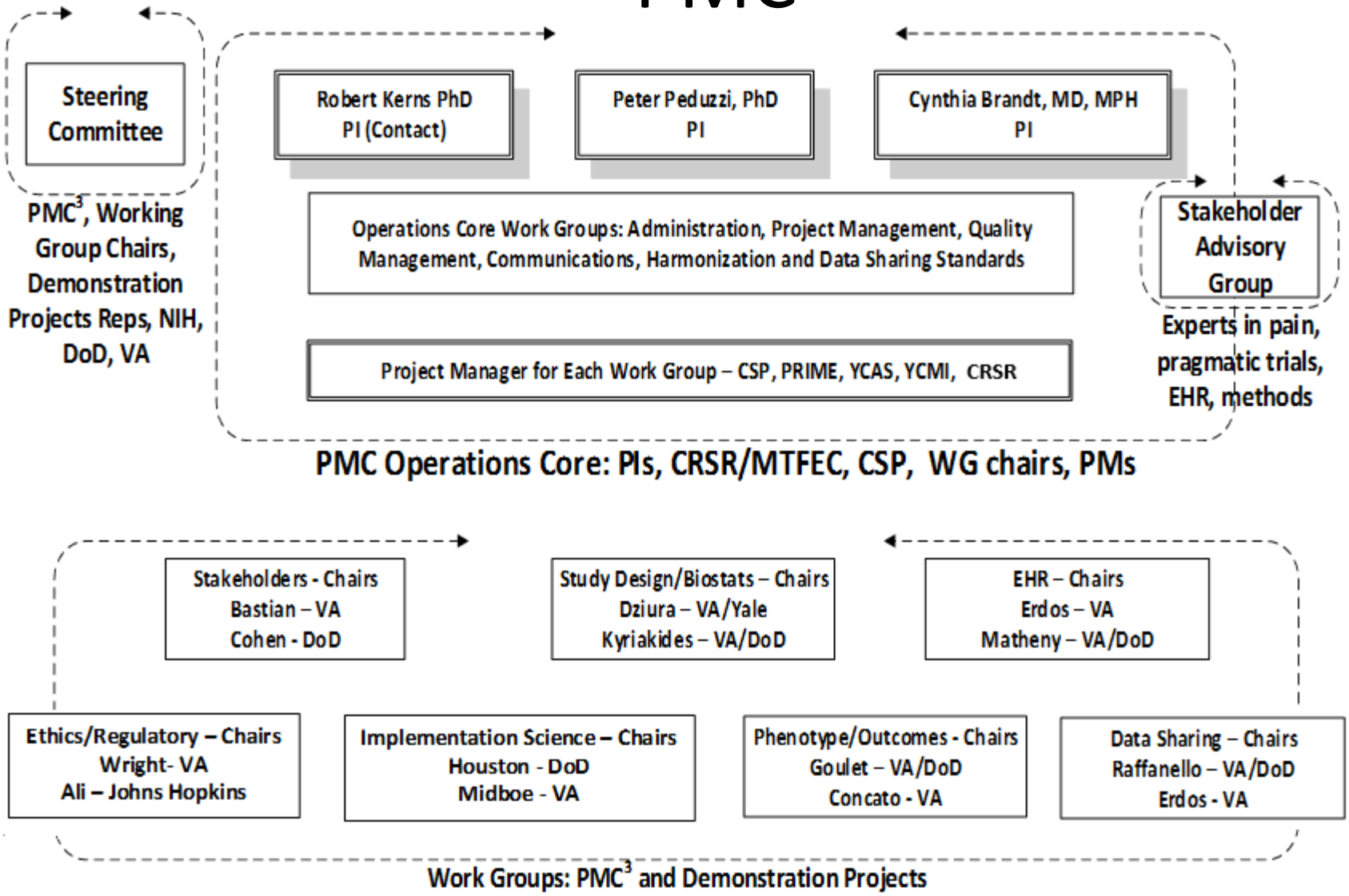
Yale Center for Analytic Sciences (YCAS)

- Scientific expertise in Biostatistics; multi-site pragmatic trial design, execution and analysis and Data Science
- Expertise in phenotyping and outcomes research
- Expertise in data management; data coordinating center expertise for large, multi-site trials

Yale Center for Medical Informatics (YCMI)

- Scientific expertise in Informatics and Data Science including development and use of EHRs for clinical care and research, clinical decision support, data modeling, storage, retrieval, extraction, data standards, ontologies and vocabularies, data sharing and security, NLP, ML, bioinformatics
- Expertise in multiple EHRs, standards, data integration, ontologies
- Expertise and collaborators in VA and DoD EHRs phenotyping using EHR, modeling of VA EHR into national corporate data warehouse with Observational Medical Outcomes Partnership (OMOP), modeling of DoD EHR data

PMC^3


Steering Committee
PMC3, Working Group Chairs, Demonstration Projects Reps, NIH, DoD, VA
Robert Kerns PhD
PI (Contact)
Peter Peduzzi, PhD
PI
Cynthia Brandt, MD, MPH
PI
Operations Core Work Groups: Administration, Project Management, Quality Management, Communications, Harmonization and Data Sharing Standards
Project Manager for Each Work Group – CSP, PRIME, YCAS, YCMI, CRSR
Stakeholder Advisory Group
Experts in pain, pragmatic trials, EHR, methods
PMC Operations Core: PIs, CRSR/MTFEC, CSP, WG chairs, PMs
Stakeholders - Chairs
Bastian – VA
Cohen - DoD
Study Design/Biostats – Chairs
Dziura – VA/Yale
Kyriakides – VA/DoD
EHR – Chairs
Erdos – VA
Matheny – VA/DoD
Ethics/Regulatory – Chairs
Wright- VA
Ali – Johns Hopkins
Implementation Science – Chairs
Houston - DoD
Midboe - VA
Phenotype/Outcomes - Chairs
Goulet – VA/DoD
Concato - VA
Data Sharing – Chairs
Raffanello – VA/DoD
Erdos - VA
Work Groups: PMC3 and Demonstration Projects

PMC Working Groups

- Electronic Health Record
- Stakeholder Engagement
- Phenotypes/Outcomes
- Ethics/Regulatory
- Study Design/Biostatistics
- Data Sharing
- Implementation Science

- Chairs from Coordinating Center
- Investigators from Demonstration Projects
- Representatives from NIH, DoD, and VA

- Purpose:
  - Guide and support Demonstration Projects
  - Disseminate knowledge

Biostatistics and Study Design

Goals and Objectives:

- Provide guidance on methodological standards in the design and implementation of non-pharmacologic pragmatic trials of pain management.
- Collaborate with demonstration projects during planning and execution phases to ensure efficient and robust study design and analysis plans.
- Review proposed data processes to ensure that collection of all required individual-level data are feasible and well described.
- Work with collaborators, investigators and academic institutions to collate and disseminate statistical and methodological issues arising from review of the demonstration projects.
- Facilitate methodological work in response to issues identified through demonstration project review.

Phenotype and Outcomes

Goals and Objectives:

- Identify reliable and clinically meaningful phenotypes among participants, for use in examining important treatment effect moderators and for enhanced understanding of study results.
- Promote harmonization of measurement approaches, when feasible, especially for key outcomes proposed.
- Provide a forum for discussing analytic, technical, and regulatory issues that arise related to harmonization of measurement approaches.

Executive Committee

- **Co-Chairs**
  - NCCIH – Dr. David Shurtleff, NCCIH Deputy Director
  - DoD - COL Ann Nayback-Beebe, Director CRMRP
  - VA - Dr. David Atkins, Director, Health Services Research

- **Co-Funding Agency Representatives**
  - NINDS – Dr. Walter Koroshetz
  - NIDA – Dr. Wilson Compton
  - NIAAA – Dr. Mark Egli
  - NINR – Dr. Martha Matocha
  - NICHD/NCMRR – Dr. Alison Cernich
  - OBSSR – Dr. Wendy Smith
  - ORWH – Dr. Lisa Begg

Agency Oversight Staff

- NCCIH – Drs. Emmeline Edwards, Cathy Meyers, Wendy Weber, Dave Clark, Lanay Mudd, and Sara Rue
- DoD – Drs. Pete Murray, Ron Hoover, Usamah Kayyali, Claudio Ortiz, and Jami Scheib
- VA – Dr. Courtney Paolicelli

PMC Executive Committee

- Provides Quarterly updates to funding and co-funding agency leads from NIH, DoD, and VA
  - Status of overall program and lessons learned across the program
  - Update on the activities of the Coordinating Center
  - Highlight outcomes such as publications or presentations
  - Receives guidance for direction of the program

- Co-Chairs will make funding decisions about program continuance, transition to second phase of funding for trials, and/or expansion with input from other agency co-funders

PMC Progress

Project Milestones

- Individual demonstration project planning phase milestones have been reviewed and approved by their respective funding agencies

Core Working Groups

- All working groups have been established and hold teleconferences with demonstration project representatives; some provide individual consultation

Harmonization

- All projects have agreed to include the PEG3 as an outcome measure
  - Discussions are ongoing to agree on a definitions of chronic pain, opioid exposure, CIH uptake, among other operational definitions

Site Overlap

- Projects that plan to recruit or perform interventions at the same locations developed plans to address and minimize competition for subjects and possible contamination

Steering Committee Meetings

- Monthly SC meetings are held
- Two Face-to-Face SC meetings have been held
  - Next meeting May 14-15, 2019 in Bethesda

Thanks

Robert.Kerns@yale.edu

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