NIH Collaboratory

Health Care Systems Research Collaboratory

pcornet

The National Patient-Centered Clinical Research Network

Grand Rounds, A Shared Forum of the NIH Collaboratory and PCORnet

Rethinking Clinical Research®

painmanagement collaboratory

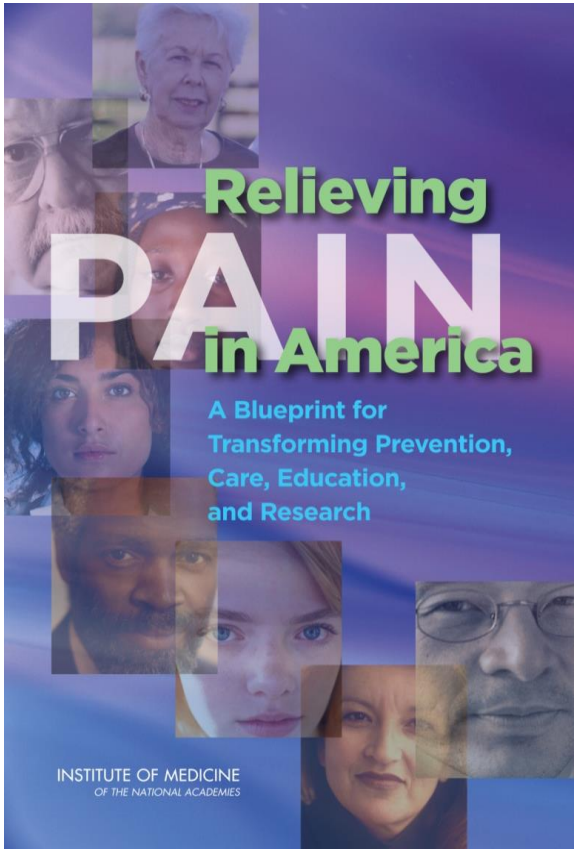
HHS-DoD-VA Pain Management Collaboratory

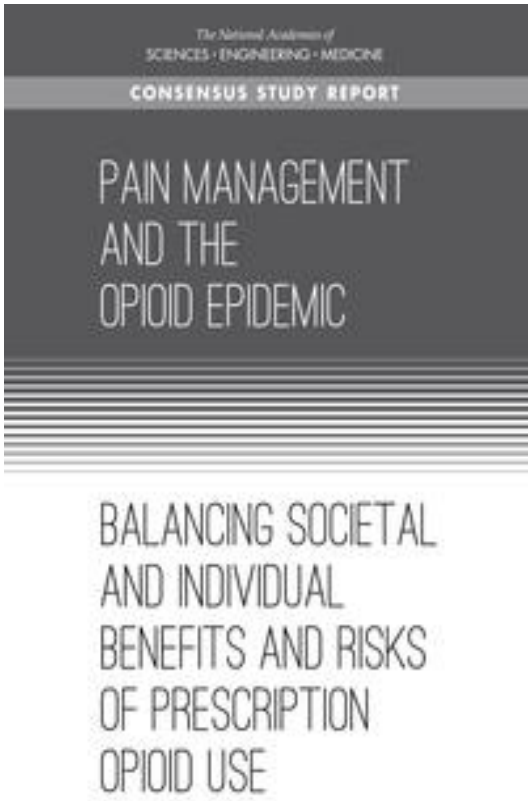
Robert Kerns, PhD
Peter Peduzzi, Ph.D.
Cynthia Brandt, M.D., M.P.H

Disclosures

- Research support
  - Department of Veterans Affairs
  - National Institutes of Health
  - Patient-Centered Outcomes Research Institute
  - Consortium of Multiple Sclerosis Centers
- Other disclosures
  - Quantia MD (Fee for on-line presentation)
  - Quintiles (Consulting fee)
  - Mathematica (Consulting fee)
- 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.

Public health perspective





Continue today's conversation on Twitter. Follow us: @Collaboratory1 and @PCORnetwork

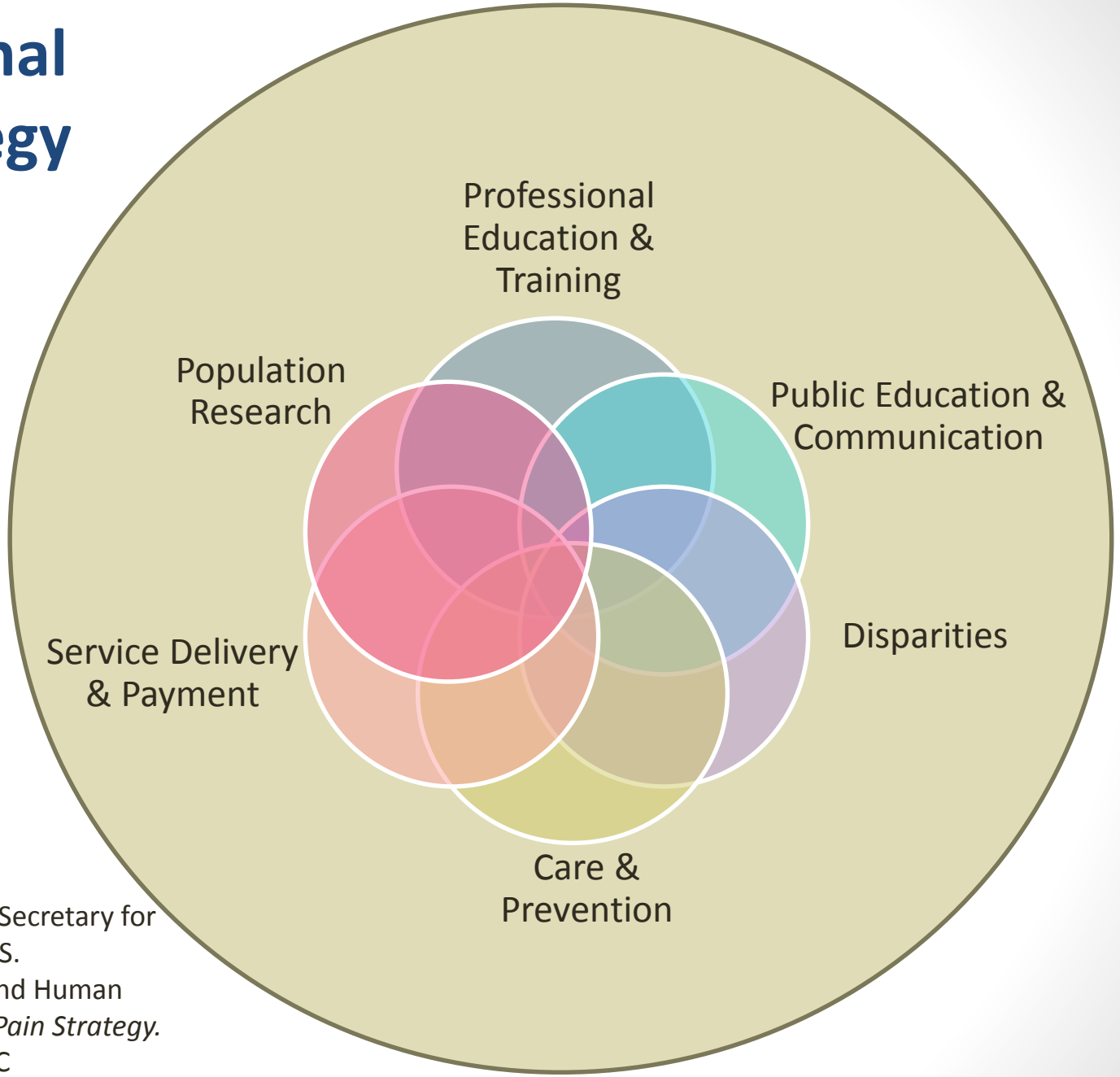
Pain as a public health problem: Magnitude of the problem

- As many as 1/3 of the US adult population report chronic pain
- Pain conditions are among the most disabling health problems
- Costs of pain are estimated at $500 billion/year
- Disparities in pain prevalence and care are well documented
- Military service members and Veterans are particularly vulnerable subgroups

Pain as a public health problem: Military Service Members and Veterans

- Approximately 45% of active duty military service members report pain (Toblin et al, 2014)
- 50-75% of US military Veterans experience persistent pain (Kerns et al., 2003; Haskell et al., 2006; Nahin, 2017)
- Veterans with pain, compared to non-Veterans with pain, report more severe pain (Nahin, 2017)
- The proportion of Veterans in care in VHA with painful musculoskeletal conditions is steadily increasing over time (Goulet et al., 2016)
- Pain is among the most costly disorders treated in VHA settings (Yu et al., 2003)

The National Pain Strategy



The Office of the Assistant Secretary for Health at the U.S. Department of Health and Human Services. (2016). *National Pain Strategy.* Washington, DC

Integrated, patient-centered, evidence-based, multimodal, and interdisciplinary pain care

From the NPS:

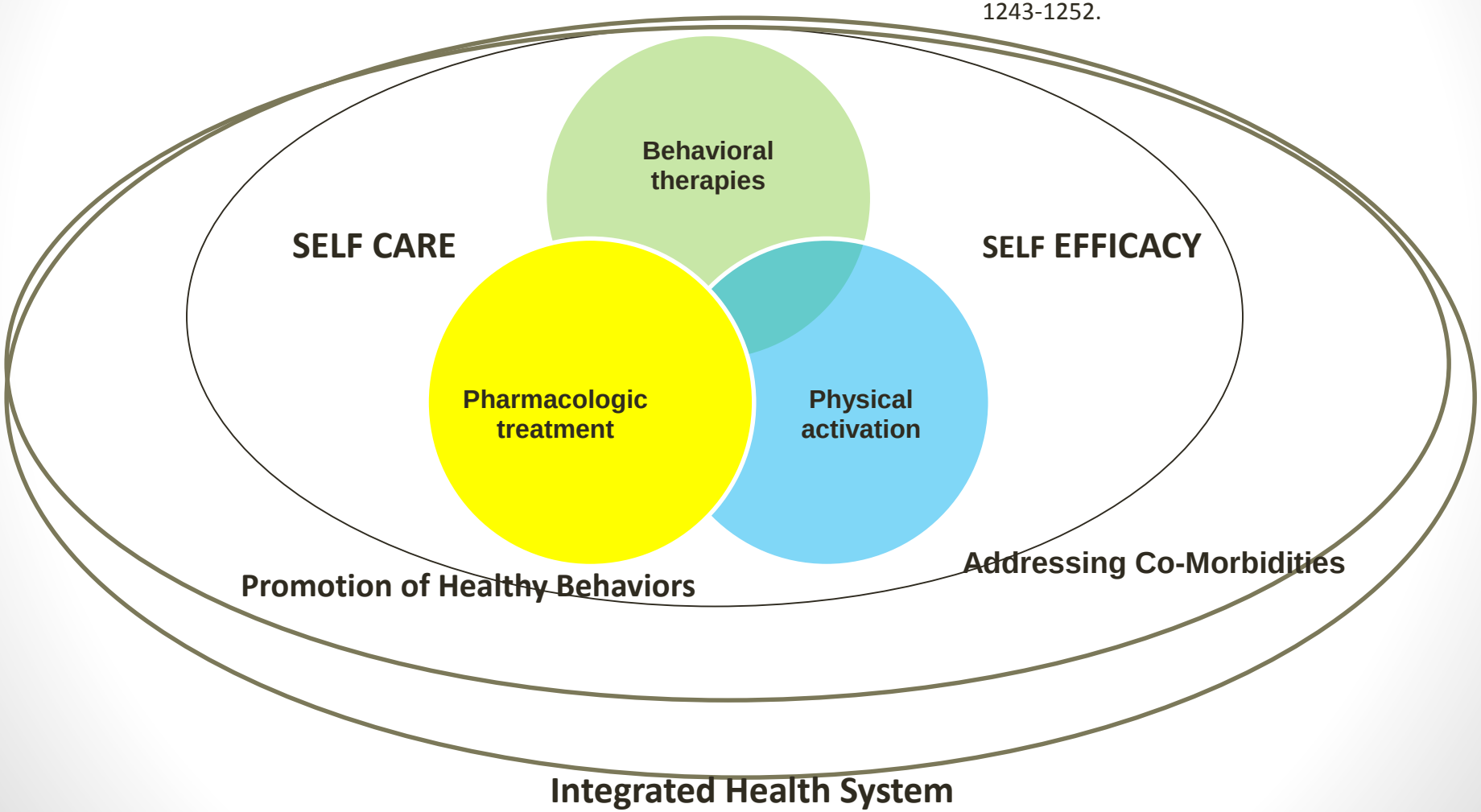
Integrated care is the systematic coordination of medical, psychological and social aspects of health care and includes primary care, mental health care, and, when needed, specialist services.

Integrated Pain Clinic team at the
VA Connecticut Healthcare System

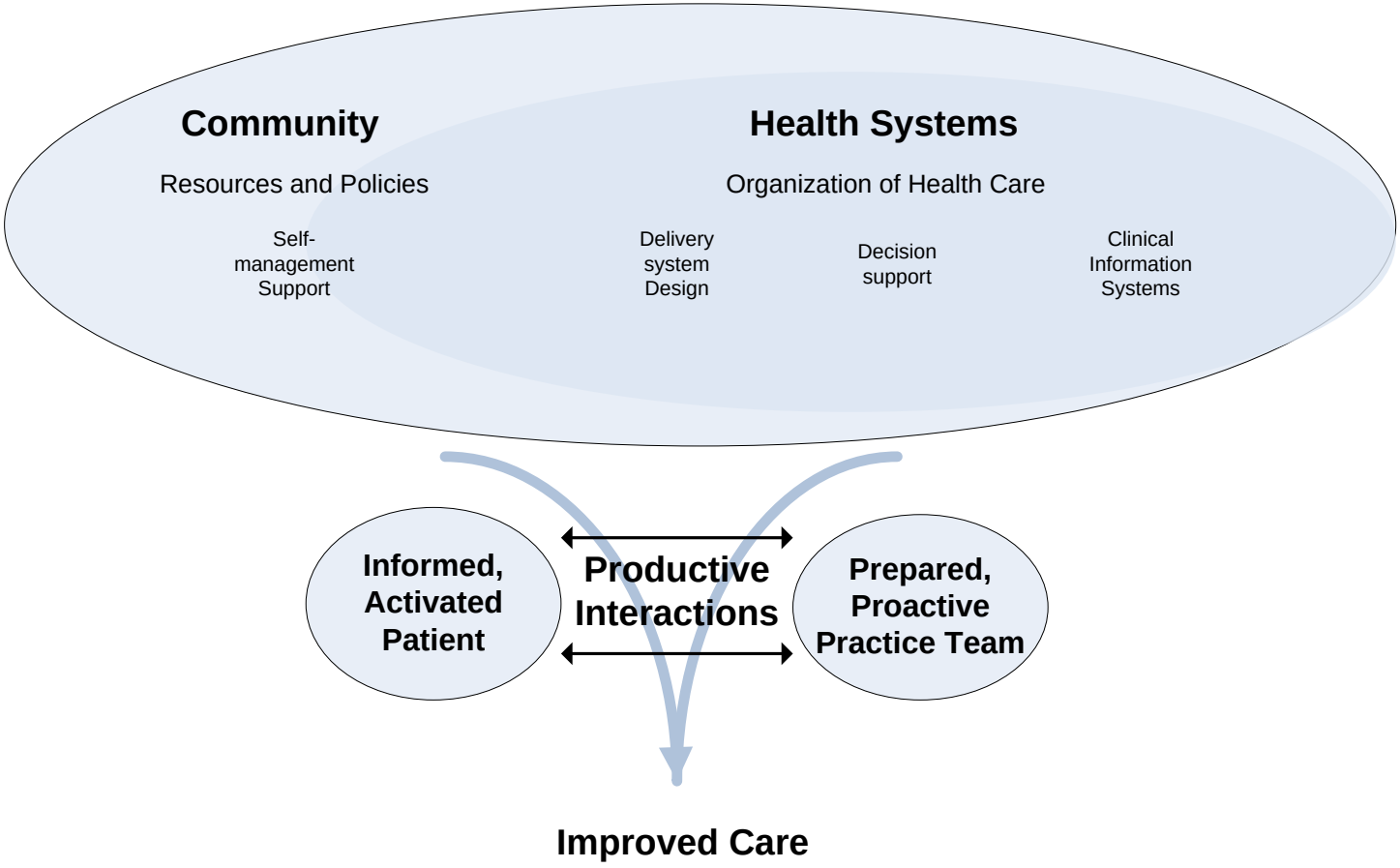
Continue today's conversation on Twitter. Follow us: @Collaboratory1 and @PCORnetwork

Biopsychosocially-informed multimodal treatment plan

Adapted from Dobscha et al. (2009). Collaborative care for chronic pain in primary care: A cluster-randomized trial. *JAMA, 301,* 1243-1252.



Chronic Care Model



Wagner, E.H. (1998). Chronic disease management: What will it take to improve care for chronic illness. Effective Clinical Practice, 1, 2-4.

Center for Disease Control Guidelines – March, 2017

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CLINICAL REMINDERS

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient

1 Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

American College of Physicians Guidelines – Feb, 2017

CLINICAL GUIDELINE

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians*

1) Acute/sub-acute: non-pharmacological (e.g., heat, massage, acupuncture, spinal manipulation)
2) Chronic: non-pharmacological (e.g., exercise, multidisciplinary rehab, mindfulness-based stress reduction, cognitive-behavioral therapy)
3) Chronic: if no response to above, NSAIDs (first line), anti-depressants, low-level opioids (2nd line), opioids (last resort)

Federal Pain Research Strategy

https://iprcc.nih.gov/FPRS/FPRS.htm

Cross cutting priority: EFFECTIVE MODELS OF CARE DELIVERY FOR PAIN MANAGEMENT

Statement of the Problem: ***Despite the significant burden of pain, effective programs, services, and interventions are not always accessible, available, or utilized.***

Recommendation: ***Develop, Evaluate, Improve Models of Pain Care.***

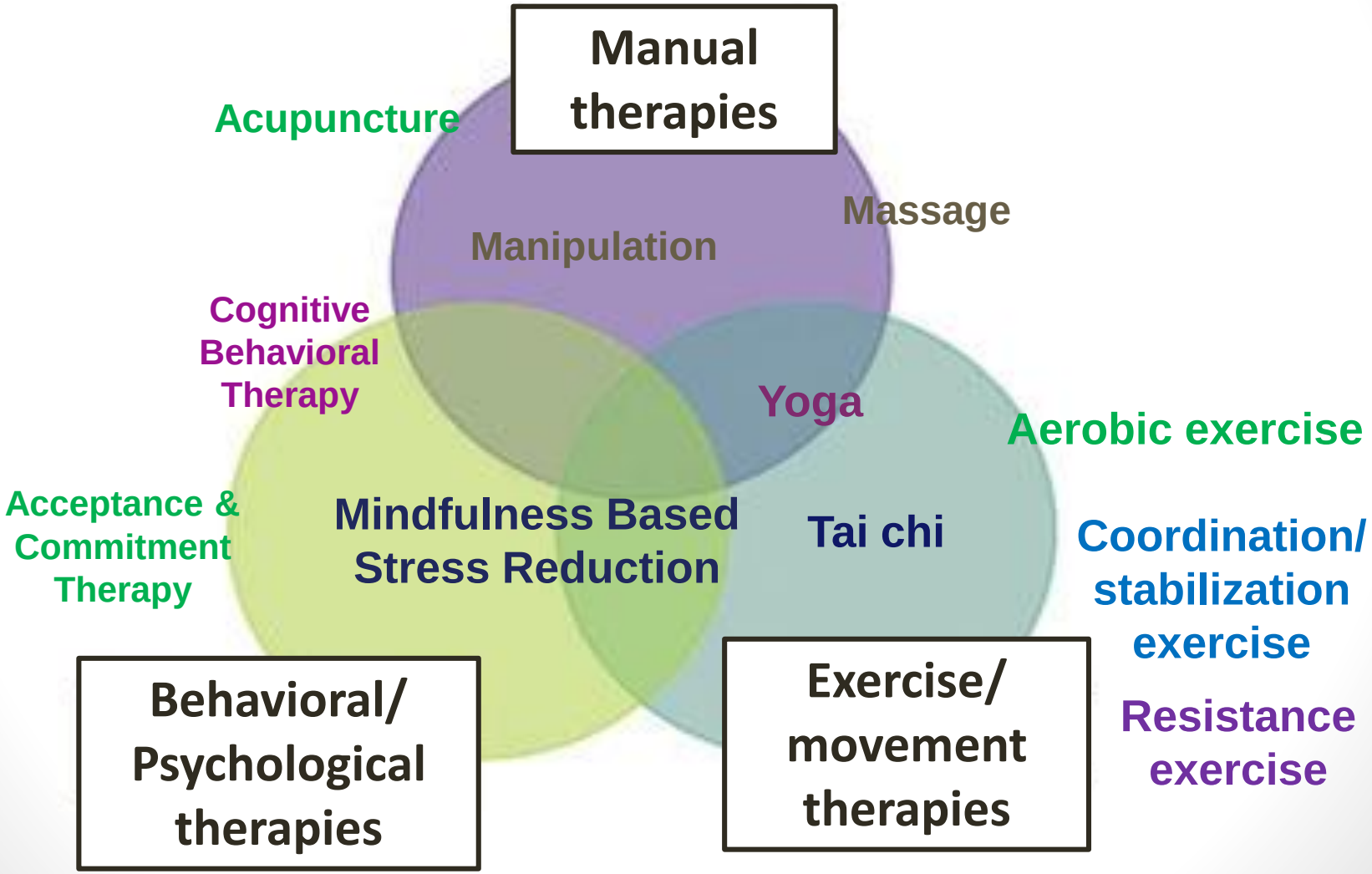
- Research is needed to develop new or improve current models of primary, secondary, tertiary care to improve pain management along the continuum of the pain experience.
- Research should include studies on models of integrated care, team care delivery, and reimbursement innovations.

STATE OF THE ART CONFERENCE

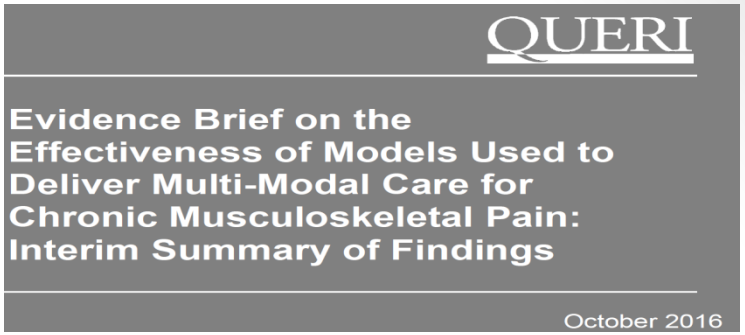
Non-pharmacological Approaches to Chronic Musculoskeletal Pain Management

VA HSR&D

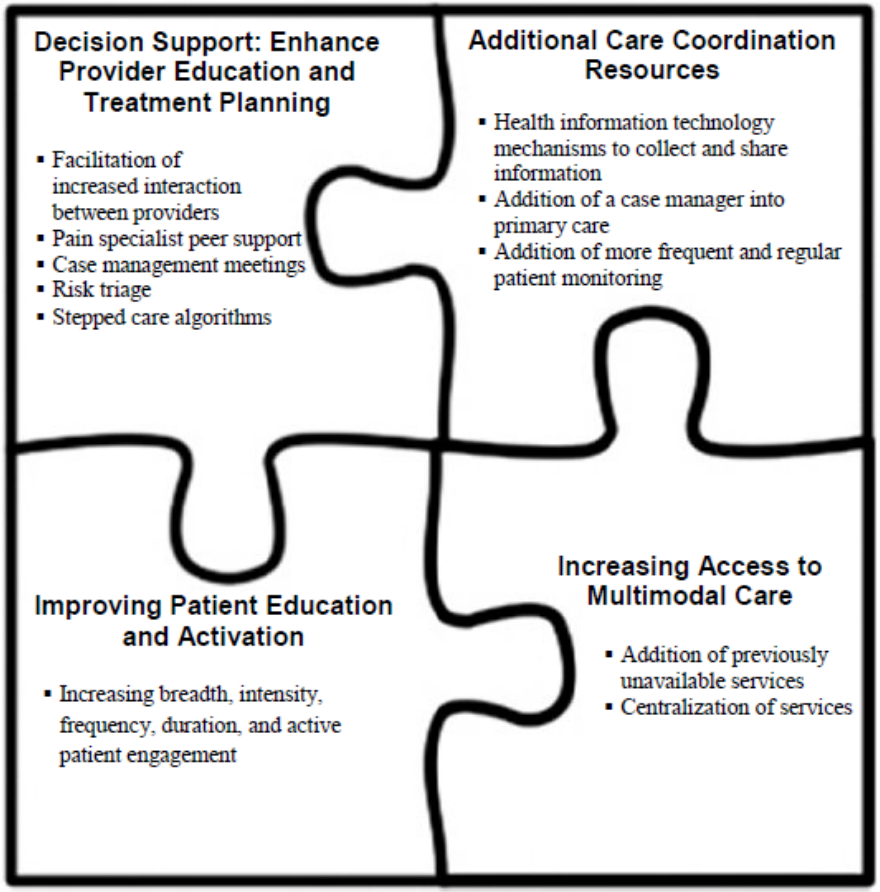
Non-pharmacological approaches ready for implementation



Models for pain care delivery

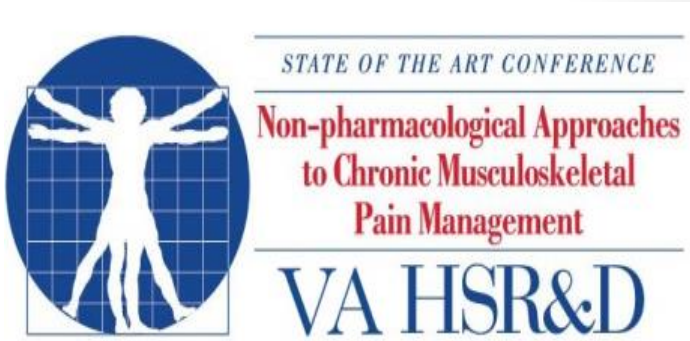


- 11 articles (10 studies) included
- Most were RCTS of fair-good quality (3 poor)
- Most had 12 month follow-up (range 6-18)
- Most used usual care control
- Baseline mean pain 5.1-7.7 on 10-point scale
- 9 diverse models of care delivery



Peterson K, et al. (2017). Evidence Brief: Effectiveness of Models Used to Deliver Multimodal Care for Chronic Musculoskeletal Pain. VA ESP Project #09-199.

Targets for Improvement



- Increase positive effects
- Improved access
- Successful engagement
- Reduced drop-out
- Enhanced adherence to treatment recommendations
- Maintenance of treatment gains
- Relapse prevention
- Patient-treatment matching to maximize benefits
- Increased attention to comorbidities

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

Continue today's conversation on Twitter. Follow us: @Collaboratory1 and @PCORnetwork

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

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

HHS-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), OBSSR, ORWH, NINR
  - DoD: Clinical and Rehabilitative Medicine Research Program (CRMRP), Military Operational Medicine Research Program (MOMRP)
  - VA: Health Services Research and Development (HSRD)

Continue today's conversation on Twitter. Follow us: @Collaboratory1 and @PCORnetwork

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

Pain Management Collaboratory

HHS, DOD, VA Sponsors and Scientific Officers

11 Pragmatic Studies and Teams
From CA, NC, CT, WA, OR, TN, MD, MA, MN, TX

Pain Management Collaboratory Coordinating Center PMC3 –
From TN, OR, MD, CT, NC, DC

Coordination Through and Participation in:

Work Groups
Biostats Design, Phenotypes & Outcomes,
Stakeholders, EHR,
Data Sharing, Regulatory and Ethics

Steering Committee

Veteran and Military Service Member Engagement
External Stakeholder Groups

The Pragmatic 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 and 2-4 year implementation phase.
- All projects are milestone-driven, and moving to the implementation phase will be dependent upon the successful progress made during the planning phase.
- 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 Projects (NIH funded)

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

Demonstration Projects (VA or DoD funded)

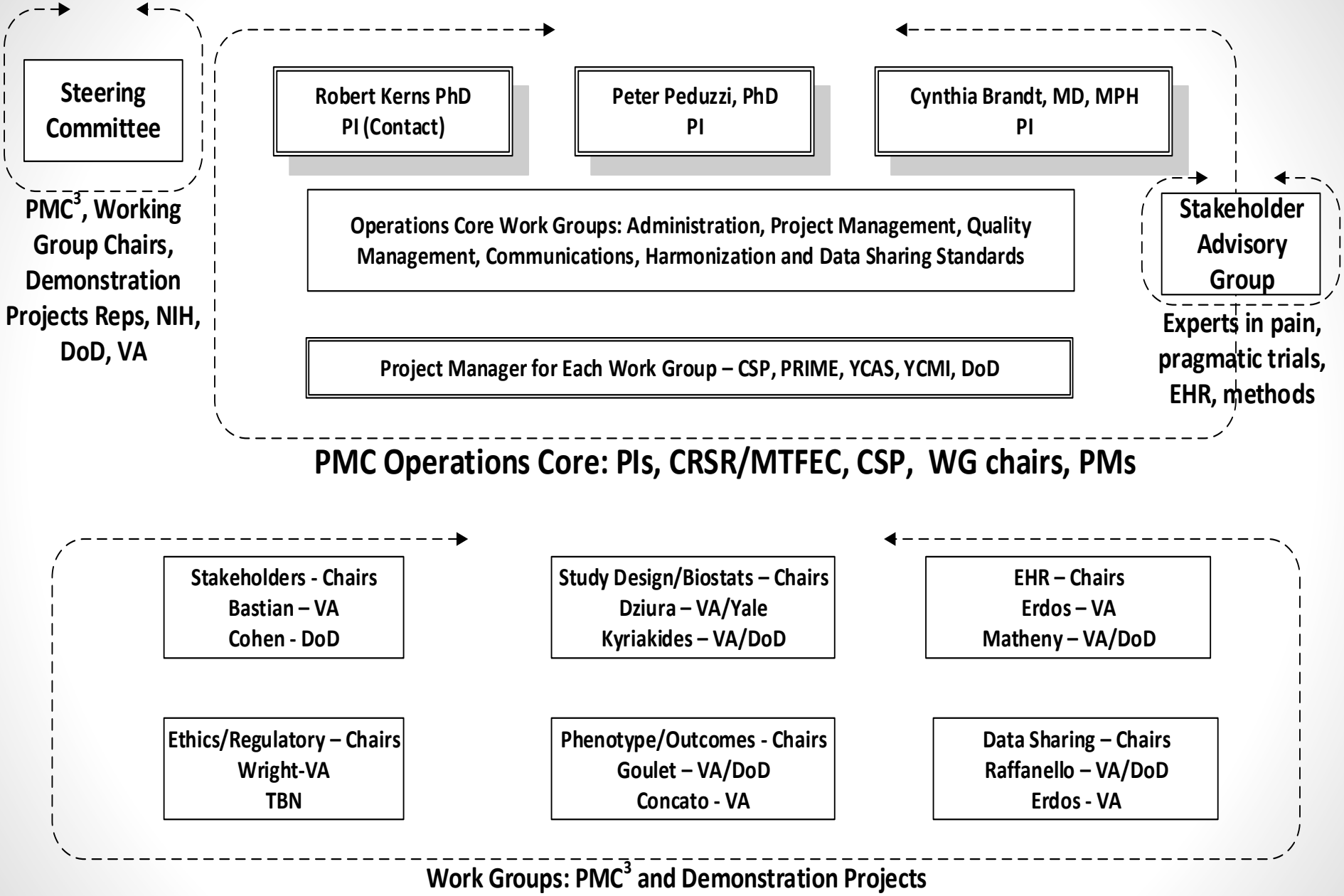
- S. Taylor/S. Zeliadt: Complementary and Integrative Health for Pain in the VA: A National Demonstration Project (VA)
- D. Burgess: Testing Two Scalable, Veteran-Centric Mindfulness-Based Interventions for Chronic Musculoskeletal Pain: A Pragmatic, Multisite Trial (DoD)
- S. Farrokhi/C. Dearth: Resolving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

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

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.


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, DoD
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
TBN
Phenotype/Outcomes - Chairs
Goulet – VA/DoD
Concato - VA
Data Sharing – Chairs
Raffanello – VA/DoD
Erdos - VA
Work Groups: PMC3 and Demonstration Projects

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

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

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

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

Updates and summary

Demonstration Projects

- Seven of 11 Demonstration Projects have received funding notices
- All but two projects have received internal (PMC^3) feedback about study design and biostatistics
- All but one project are engaged in WGs; WGs meeting at regular intervals
- Initial decisions regarding outcomes are close to finalized

PMC^3

- Received funding notice in 9/17
- Internal operations core established
- All WGs are operational
- Website in development
- Steering Committee established; F2F meeting held in January, 2018

Thanks

Robert.kerns@yale.edu

Painmanagementcollaboratory.org