painmanagement collaboratory

Moving beyond opioid therapy: The role of the NIH-DoD-VA Pain Management Collaboratory

Robert D. Kerns, Ph.D.
Yale University

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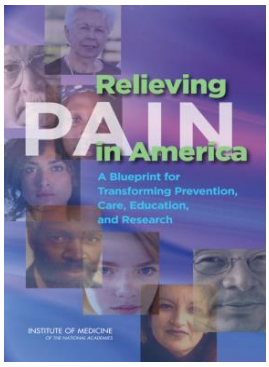
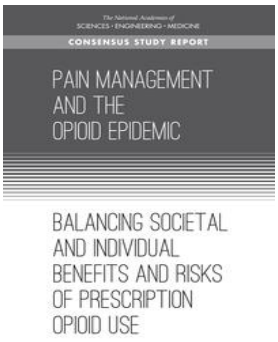
Public health perspective





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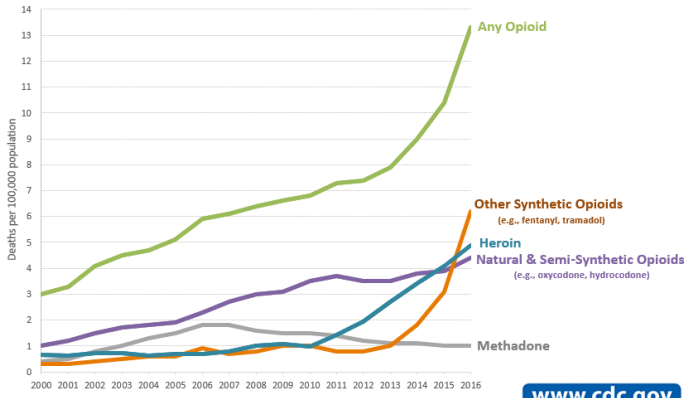
Harms related to therapeutic use of opioids is a significant contributor to the opioid crisis

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Ser vices, CDC; 2017. https://wonder.cdc.gov/.

www.cdc.gov
Your Source for Credible Health Information

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The Opioid Epidemic in America

The Research Behind Understanding, Preventing and Treating Addiction

ELSEVIER

Data from the U.S. National Institute on Drug Abuse indicates:*

Roughly
21-29%
of patients prescribed opioids for chronic pain misuse them

Between
8-12%
develop an opioid use disorder

An estimated
4-6%
who misuse prescription opioids transition to heroin

Approximately
80%
of people who use heroin first misused prescription opioids

* National Institute on Drug Abuse. (2017). Opioid Crisis. Retrieved May, 2017, from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis

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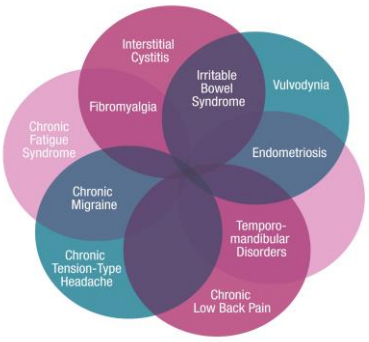
Pain as a public health problem

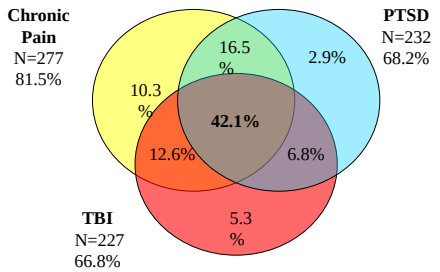
- In 2016, an estimated 20.4% (50.0 million) of U.S. adults had chronic pain (CP) and 8.0% (19.6 million) had high impact chronic pain (HICP). (Dahlhamer et al., 2018)
- Higher prevalence of both CP and HICP were observed among:
  - women,
  - older adults,
  - previously but not currently employed adults,
  - adults living in poverty,
  - adults with public health insurance, and
  - rural residents (Dahlhamer et al. 2018)
- Pain conditions are among the most disabling health problems (Stewart et al., 2003)
- Costs of pain are estimated at $500-$635 billion (IOM, 2011)
- Disparities in pain prevalence and care are well documented (Green et al., 2003; Janevic et al., 2017)

Complexities of chronic pain represent management challenges

Chronic Overlapping Pain Conditions (Chronic Pain Research Alliance)

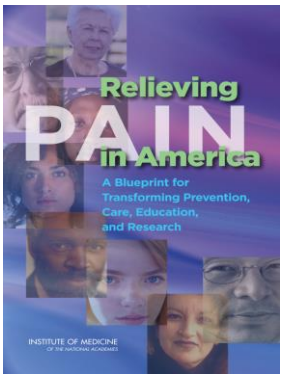


Prevalence of Chronic Pain, PTSD and TBI in a sample of 340 veterans who served in era of Afghanistan and Iraq wars



Lew, H.L. et al. (2009). Prevalence of chronic pain, posttraumatic stress disorder, and post-concussive syndrome in OEF/OIF veterans: The polytrauma clinical triad. *Journal of Rehabilitation Research and Development, 46*, 697-702.

Findings and recommendations



Pain is a biopsychosocial condition that often requires **integrated, patient-centered, evidence-based, multimodal, and interdisciplinary care.**

Efforts should span the continuum from pain prevention, through efforts to mitigate the progression of acute pain to a chronic condition and the development of high-impact chronic pain, to pain at the end-of-life.

Efforts should address all ages of the life-span.

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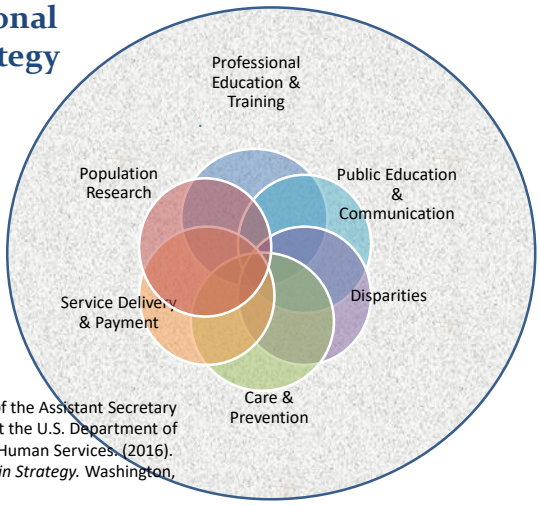
The National Pain Strategy



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

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Framework

Service Delivery & Payment
Public health entities have a role in pain care and prevention

- Many challenges exist for access to quality pain care, which is often:
  - not based on best evidence.
  - not team based.
  - limited to pharmacological treatment offered by one primary care practitioner or to procedure-oriented and incentivized specialty care.
- More quality research is needed on the effectiveness of pain interventions, integrated care, models of care delivery, and reimbursement innovations.
- We need more effective methods to disseminate research findings and incentives to incorporate them into clinical practice.
- Current reimbursement practices complicate development of a population-based approach, which would use integrated, interdisciplinary, patient-centered teams.

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Center for Disease Control Guidelines – March, 2017

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American College of Physicians Guidelines – Feb. 2017

ACP American College of Physicians
Leading Internal Medicine, Improving Lives

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)

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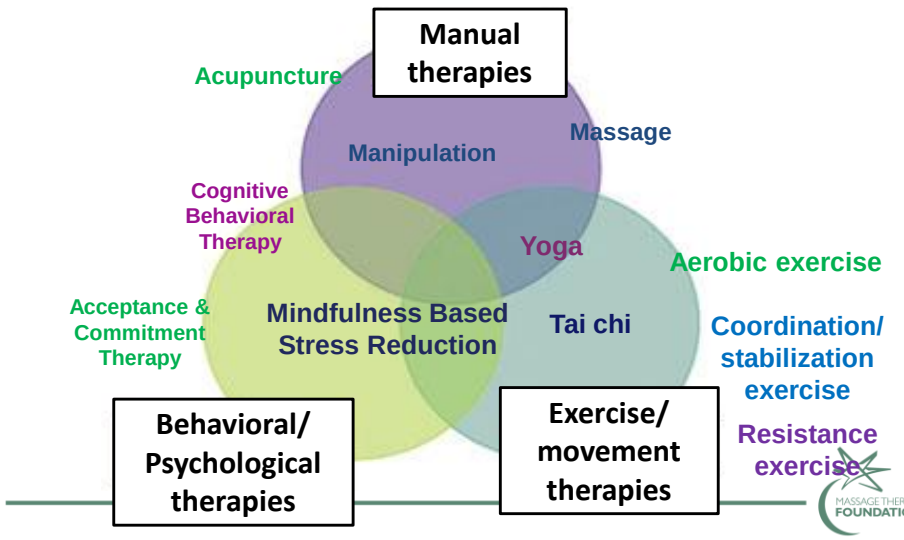
STATE OF THE ART CONFERENCE
Non-pharmacological Approaches to Chronic Musculoskeletal Pain Management
VA HSR&D

Non-pharmacological approaches ready for implementation



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Massage Therapy: Evidence for chronic pain management

- Back pain
- Neck and shoulder pain
- Headache
- Carpal Tunnel Syndrome
- Osteoarthritis
- Fibromyalgia
- Hospice

- 47% of persons who pursue massage therapy do so for medical reasons, especially for pain management
- Massage therapy is recommended by the Joint Commission, American College of Physicians and the Federation of State Medical Boards

Nahin RL, Boineau R, Khalsa PS, Stussman BJ, Weber WJ. Evidence-Based Evaluation of Complementary Health Approaches for Pain Management in the United States. Mayo Clin Proc. 2016 Sep;91(9):1292-306.

https://www.amtamassage.org/opioids?utm_source=%2finfocenter%2fhealthcare_articles-and-associations%2fMassage-Therapy-as-an-Alternative-to-Opioids.html&utm_medium=web&utm_campaign=redirect

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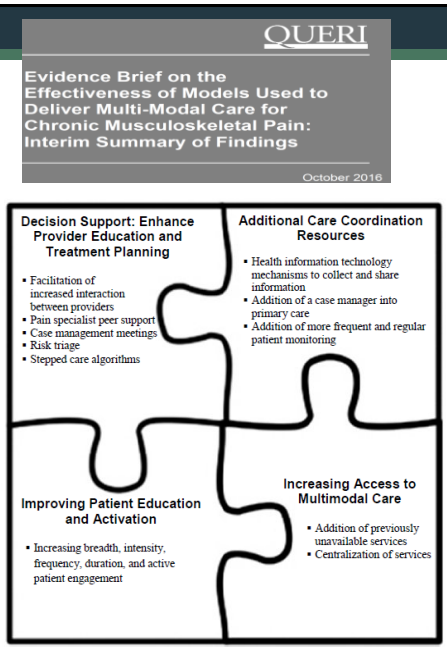
Models for pain care delivery

- 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.



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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.

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

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)

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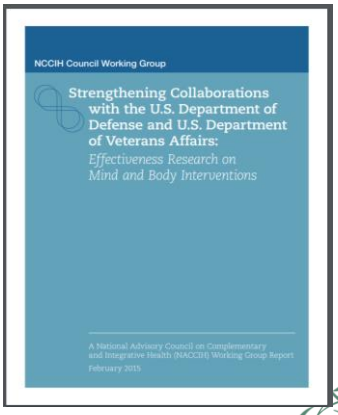
Pain Management is a high priority for the Departments of Health and Human Services (HHS), Defense (DoD) and Veterans Affairs (VA)

- 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



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NIH-DoD-VA Pain Management Collaboratory

$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

Key objectives:

- Support investigators to do the necessary planning and pilot testing to demonstrate that they can effectively implement the proposed pragmatic trial
- Conduct pragmatic clinical trials to evaluate whether non-pharmacological approaches to pain management are effective when delivered in the setting of the Veterans and/or military health care systems (VA and MHS)
  - Why pragmatic studies?
    - Emphasizes generalizability of results and protect rigor
    - Answer questions that inform VA and MHS 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
  - 2 year planning phase
  - 2 to 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 will work with their respective funding agency, and the PMC Coordinating Center coordinate resource needs and monitor progress

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

Pragmatic Clinical Trials - NIH

Julie Fritz, Dan Rhon - University of Utah
SMART Stepped Care Management for Low Back Pain in Military Health System

Steven George, Susan Hastings - Duke University
Improving Veteran Access to Integrated Management of Chronic Back Pain

Cyndy Long, Christine Goertz- Palmer College of Chiropractic
Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP

Alicia Heapy- Yale University
Cooperative Pain Education and Self-management: Expanding Treatment for Real-world Access (COPES ExTRA)

Marc Rosen, Steve Martino - Yale University
Engaging Veterans Seeking Service-Connection Payments in Pain Treatment

Karen Seal, William Becker -Northern California Institute
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

Pragmatic Clinical Trials - VA, DoD

VA Funded Pragmatic Trial:

Stephanie Taylor - VA HSR&D CSHI
Complementary and Integrative Health for Pain in the VA: A National Demonstration Project

DoD Funded Pragmatic Trials :

Diana Burgess- DoD-MOMRP
Testing two scalable, Veteran-centric Mindfulness-based Interventions for Chronic Musculoskeletal Pain: A Pragmatic, Multisite Trial

Shawn Farrokhi, Christopher Dearth - DoD-CRMRP
Resolving the Burden of Low Back Pain in Military Service Member and Veterans: A Multi-site Pragmatic Clinical Trial

Brian Ilfeld - DoD-CRMRP
Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacologic Alternative for the Treatment of Postoperative Pain

Donald McGeary, Jeffrey Goodie - DoD-CRMRP
Targeting Chronic Pain in primary Care Settings Using Internal Behavioral Health Consultants

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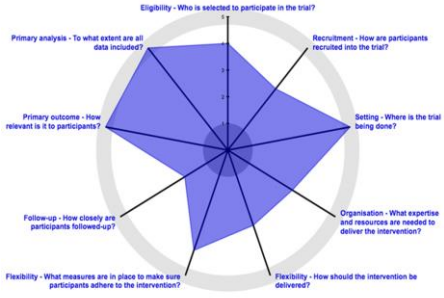
Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP (Goertz and Long)

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.**



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Pain Management Collaboratory Coordinating Center (PMC^3)

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

- 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

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PMC Working Groups

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

- Chairs from Coordinating Center
- Investigators from Pragmatic Clinical Trials
- Representatives from NIH, DoD, and VA
- Additional experts/resources

- Purpose:
  - Guide and support Pragmatic Clinical Trial teams
  - Disseminate knowledge

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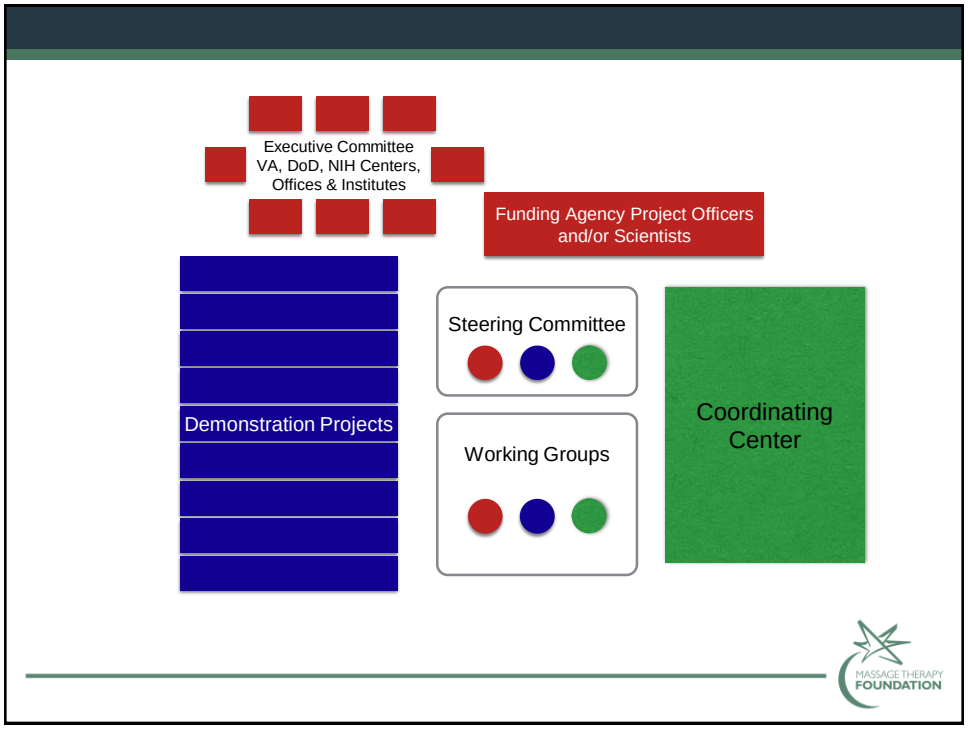

PMC Progress

Project Milestones

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

Harmonization

- All projects have agreed to include the PEG3 as an outcome measure
- Inclusion criteria and phenotyping harmonization, as appropriate to individual trials

Site Overlap

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

Website Development

- Check it out: www.painmanagementcollaboratory.org

Thanks

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