



# Complementary and Integrative Health Research: Priorities and Funding Opportunities from NCCIH

PAHO/WHO Regional Meeting

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# Author's Disclosure

Dr. Edwards is a Title 42 federal employee who is required to disclose all financial holdings as public record, and has no outside activities to disclose.



# Outline

- **NIH and NCCIH - Mission and Strategic Plans**
- NCCIH High Priority Topics
- Complementary & Integrative Health Approaches Utilization in the US
- Highlights from the NCCIH Portfolio
- Research & Training Opportunities for Investigators



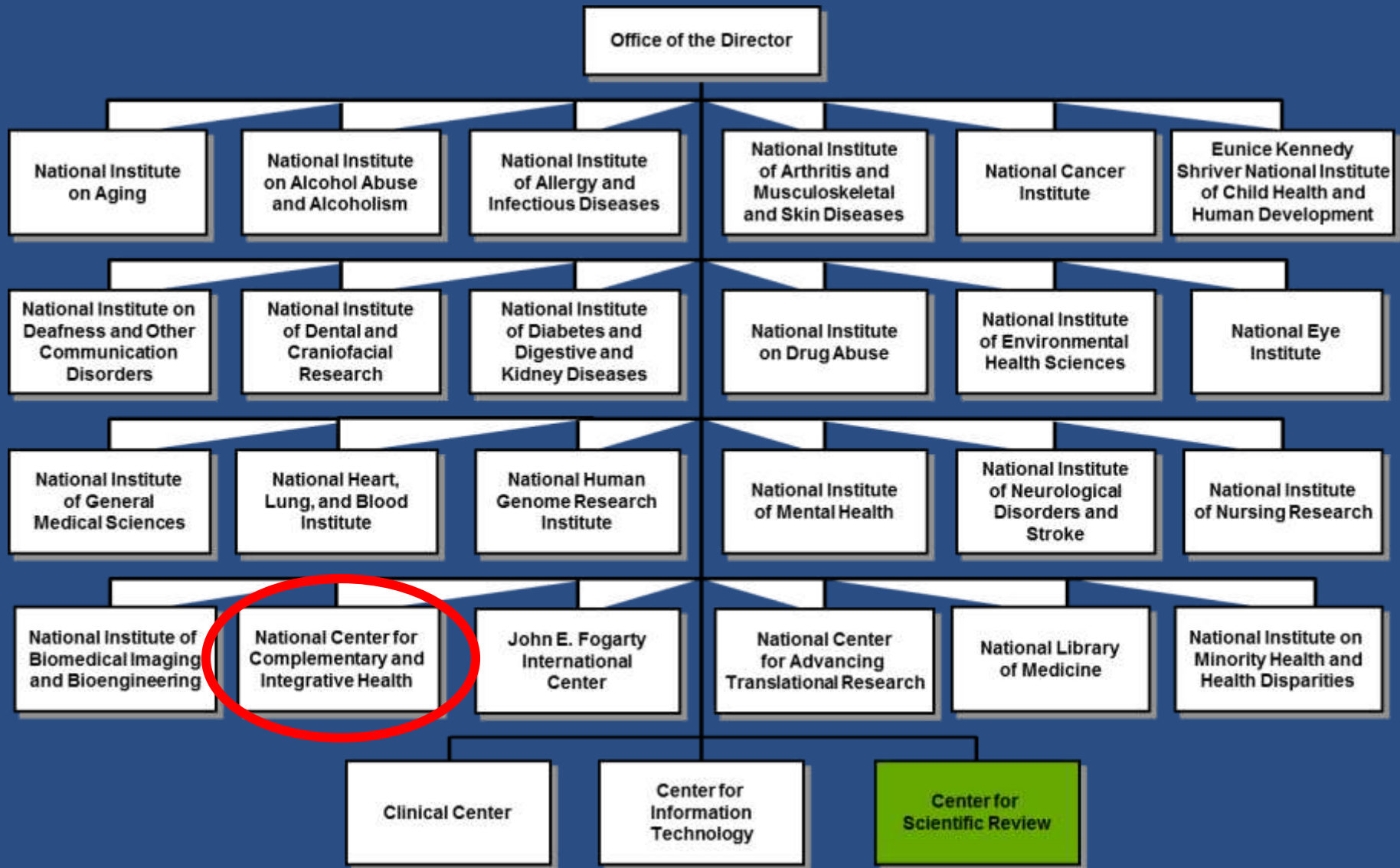


# National Institutes of Health



NIH seeks fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

# Your Application Could Be Funded by One of 24 NIH Institutes or Centers





# NIH-Wide Strategic Framework

## Overview

- Mission of NIH
- Unique moment of opportunity in biomedical research
- Current NIH-supported research landscape
- Constraints confronting the community in the face of lost purchasing power

## Fundamental Science

- Foundation for progress
- Consequences often unpredictable
- Advances in clinical methods stimulate progress
- Technology leaps catalyze advances
- Data science increases impact/efficiency

## Health Promotion/Disease Prevention

- Importance of studying healthy individuals
- Advances in early diagnosis/detection
- Evidence-based elimination of health disparities

## Treatments/Cures

- Opportunities based on molecular knowledge
- Breakdown of traditional disease boundaries
- Breakthroughs need partnerships, often come from unexpected directions

## Setting Priorities

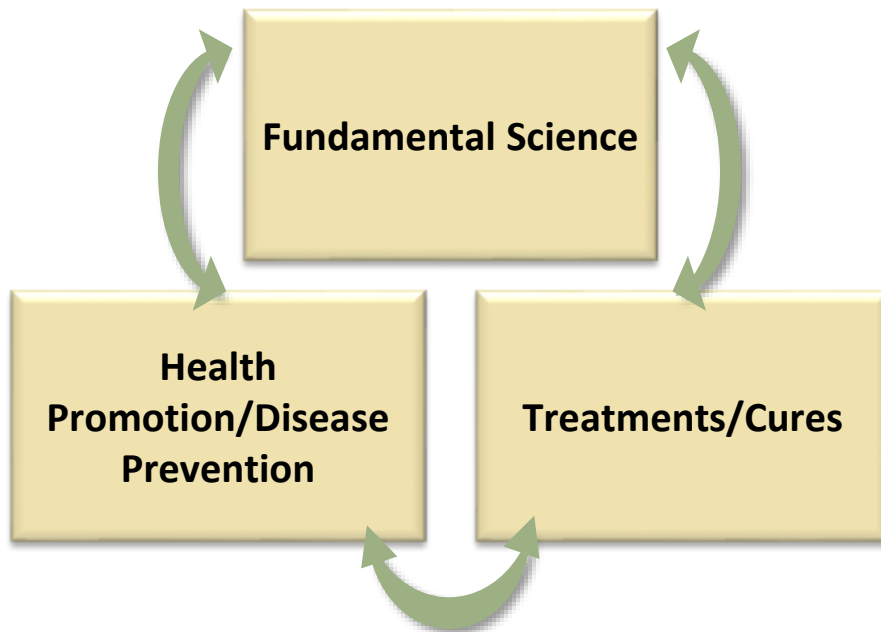
- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity; need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic

## Enhancing Stewardship

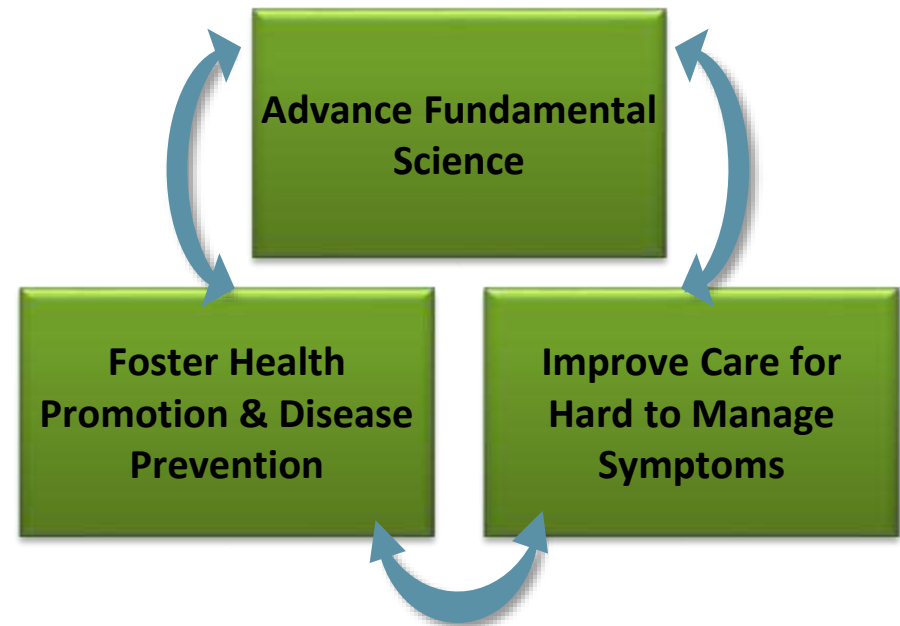
- Recruit/retain outstanding research workforce
- Enhance workforce diversity
- Encourage innovation
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden
- Employ risk management strategies

# Alignment of NCCIH Research Objectives with NIH-Wide Strategic Plan

## NIH



## NCCIH



# The NCCIH Mission

Define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative interventions and their roles in improving health and health care.

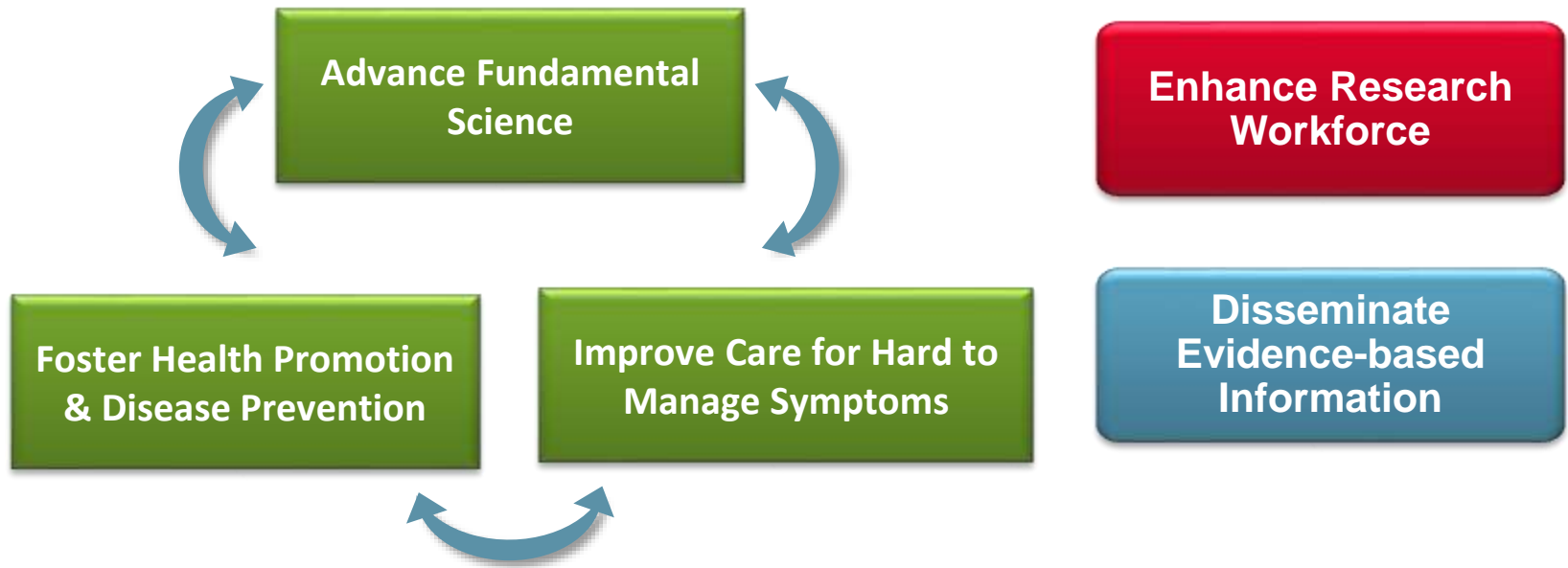




# Overview

## NCCIH Mission and Vision

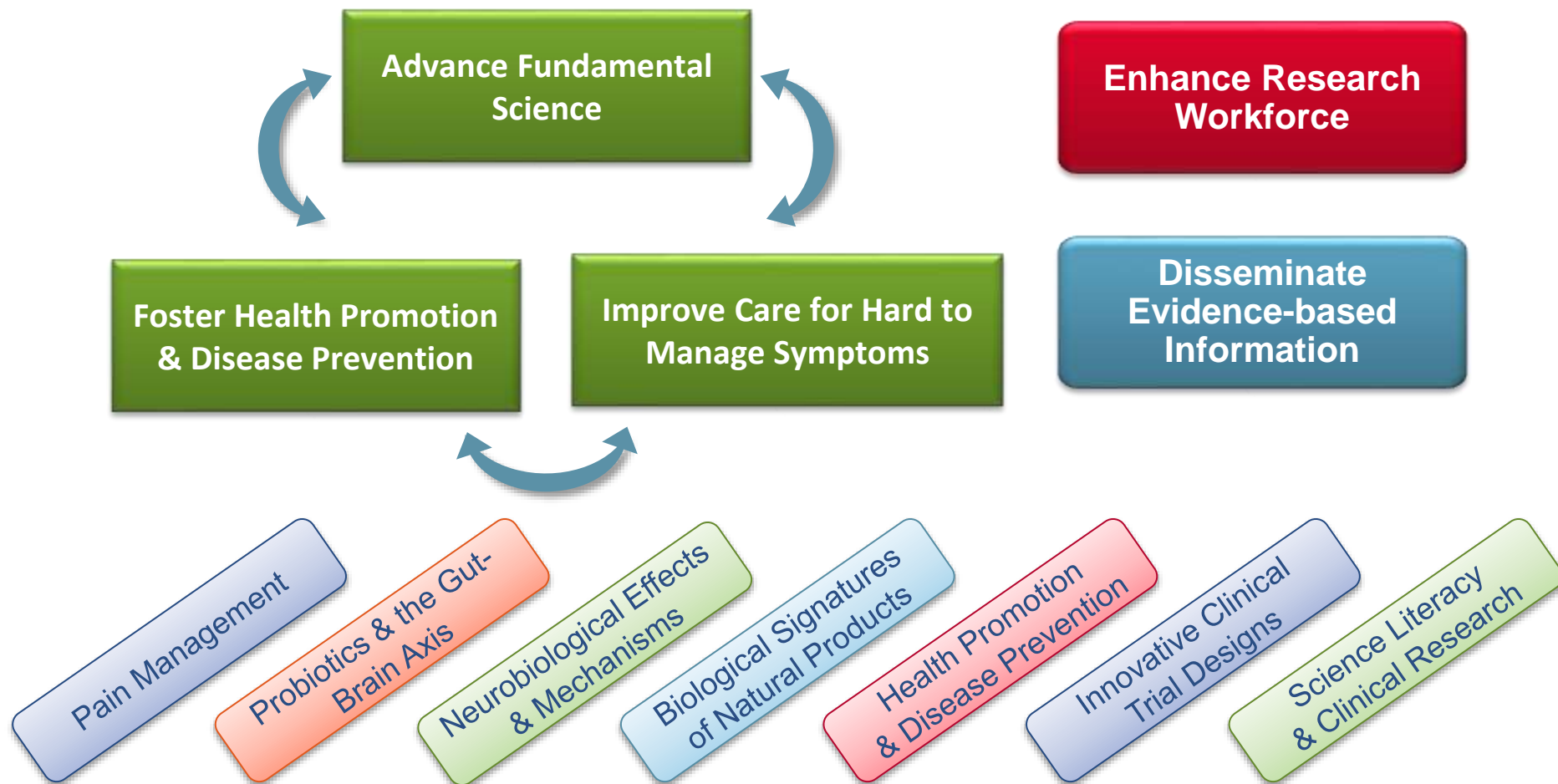
### Priority Setting



# Overview

## NCCIH Mission and Vision

### Priority Setting



# NCCIH Factors for Priority Setting

When setting research priorities NCCIH asks

- Is the topic appropriate to our mission and legislative mandate?
- Will the research meet a need not filled by other NIH programs?

## 1. Scientific Promise

How strong is the body of evidence supporting the concept?

## 2. Amenability to Rigorous Scientific Inquiry

Are there reliable and reproducible methods—e.g., diagnostics, outcome measures, biological effects, quality control, etc.?

## 3. Potential To Change Health Practices

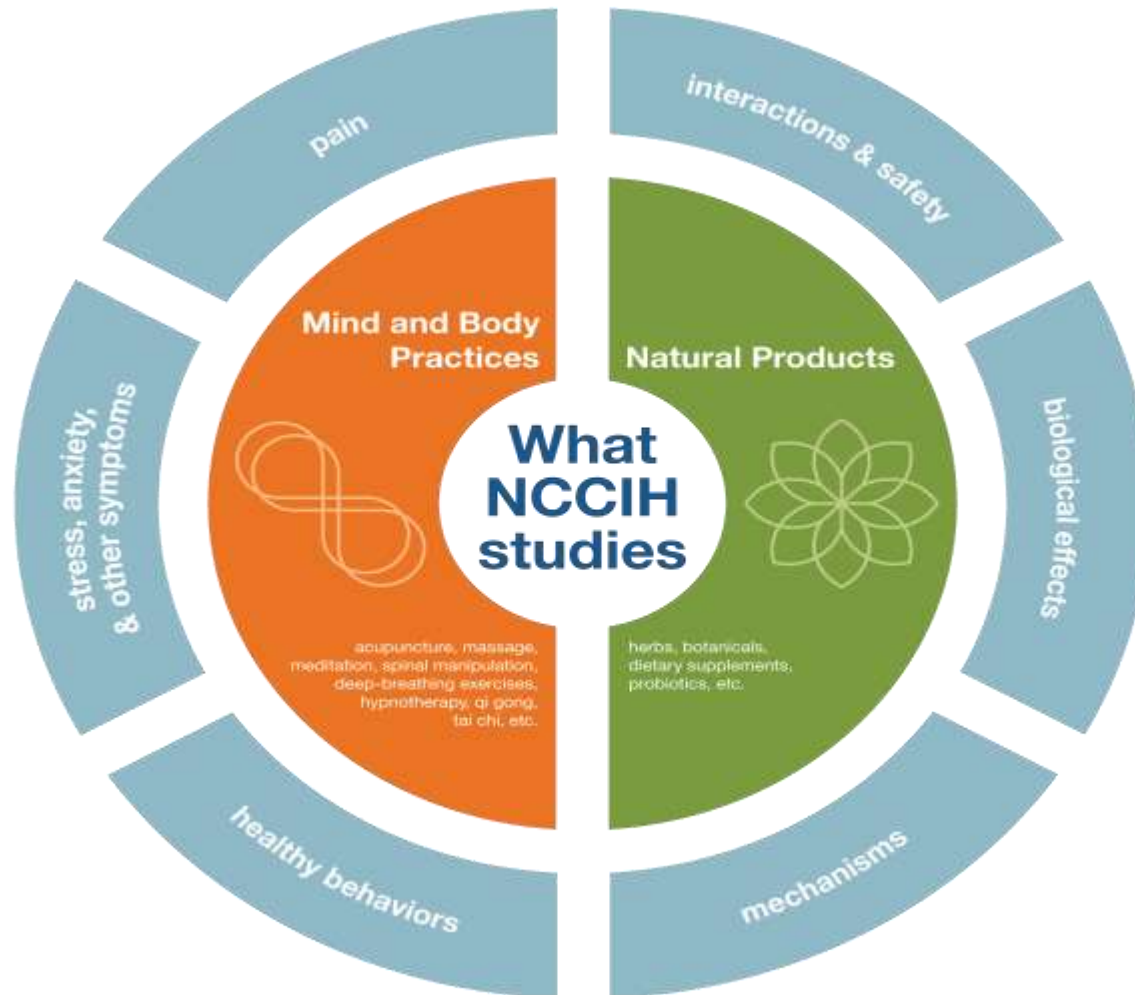
Is it reasonably likely that the results will make a difference to consumers, providers, or policymakers?

## 4. Relationship to Use and Practice

Do the methods and approaches actually address the most important questions about use or practice in the real world?

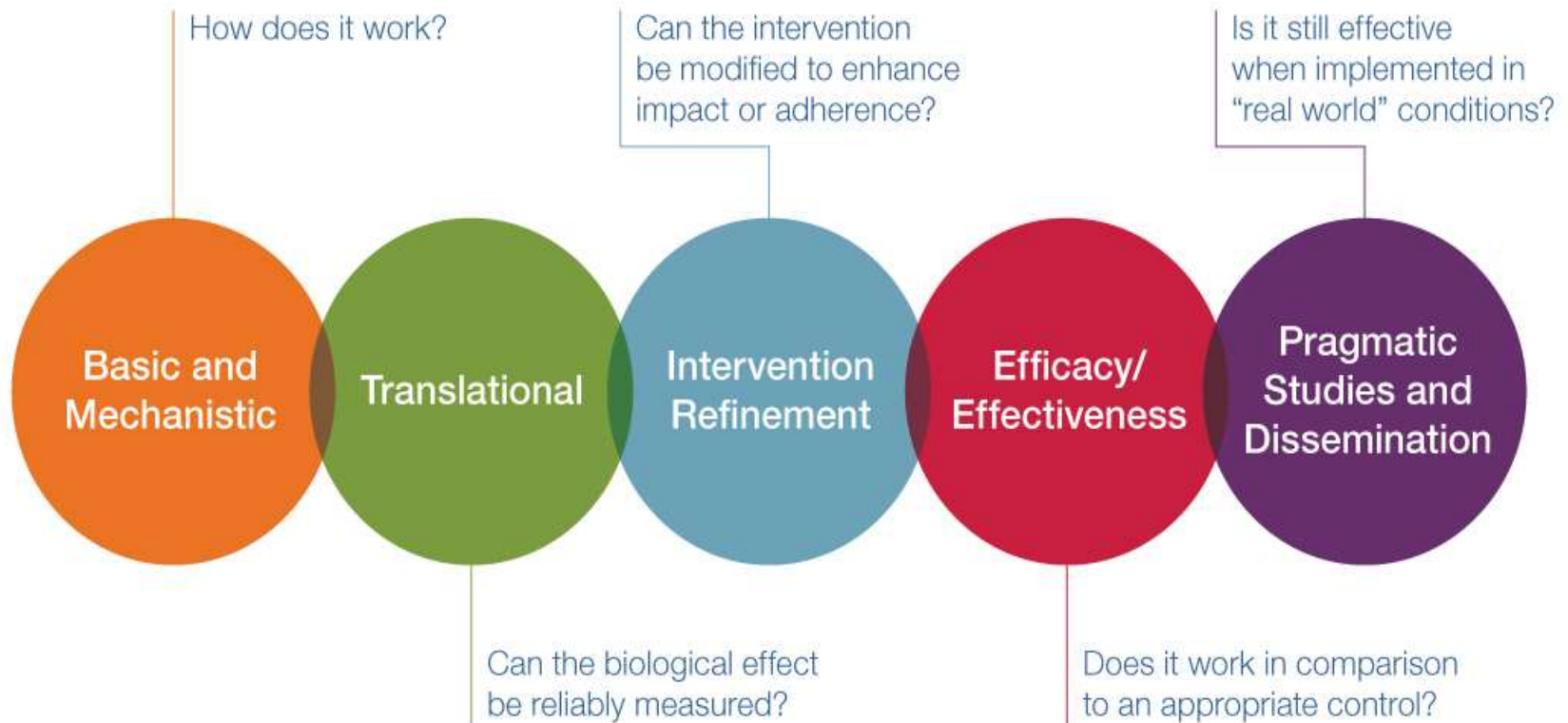


# What Does NCCIH Fund?





# NCCIH Strategic Plan Range of Research Questions



**NCCIH is unique within NIH because we focus on *interventions* rather than a disease**



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# New Directions for Mind and Body Research



- Develop and validate objective outcome measures
- Develop precise criteria or standards for specific practices
- Identify (neuro)biological mechanisms
- Research collaborations with other agencies





# New Directions for Natural Products Research

- **Center for Advancing Natural Products Innovation and Technology**
  - Develop and/or adapt cutting edge, innovative approaches and technologies that will impact on the chemical and biological investigation of natural products
- **Natural Product-Drug Interactions**
  - Identify natural products with potential to exhibit clinically significant interactions with commonly used medications
  - Establish a set of best practices
  - Provide data infrastructure to disseminate results
- **Natural Products Mechanisms of Actions**
  - Botanicals
  - Probiotics
  - Marine organisms
  - Compounds affecting brain responses



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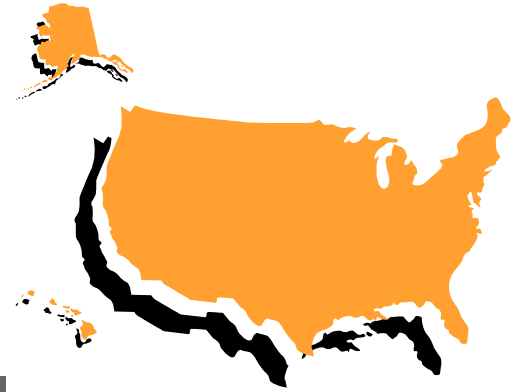


# National Health Interview Survey: Supplement on Complementary and Integrative Health Utilization

*Clarke TC et al. Trends in the use of complementary health approaches among adults in the United States, 2002 – 2012. National Health Statistics Reports; no 79. Hyattsville, MD: National Center for Health Statistics 2015*



# NHIS Sample



- All 50 states and D.C., year-round
- Oversamples Black, Hispanic, and Asian persons
- Civilian, non institutionalized population





# Background Information

U.S. population in 2012  
318 million individuals:

75.8% adults (18 or older)

24.2% children (under 18)



# Key Findings

33.2% of adults  
11.6% of children

used a complementary health  
approach in 2012

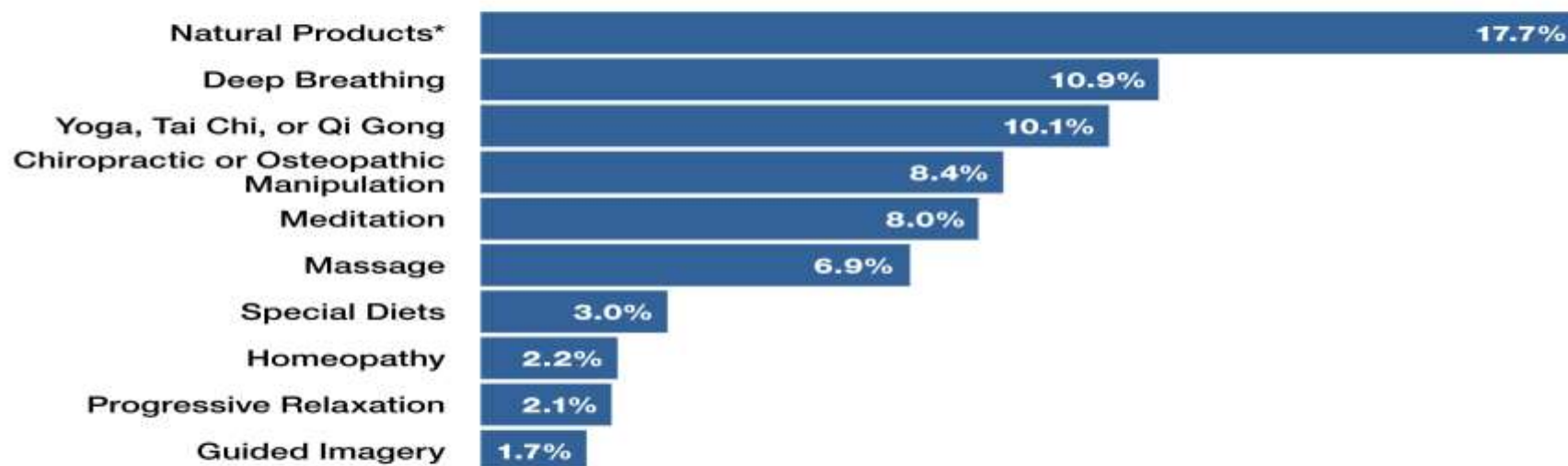


# 2012 National Health Interview Survey

## Use of Complementary Health Approaches in the U.S.

National Health Interview Survey (NHIS)

### 10 most common complementary health approaches among adults—2012



\*Dietary supplements other than vitamins and minerals.

Source: Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. Trends in the use of complementary health approaches among adults: United States, 2002-2012. National health statistics reports; no 79. Hyattsville, MD: National Center for Health Statistics. 2015.

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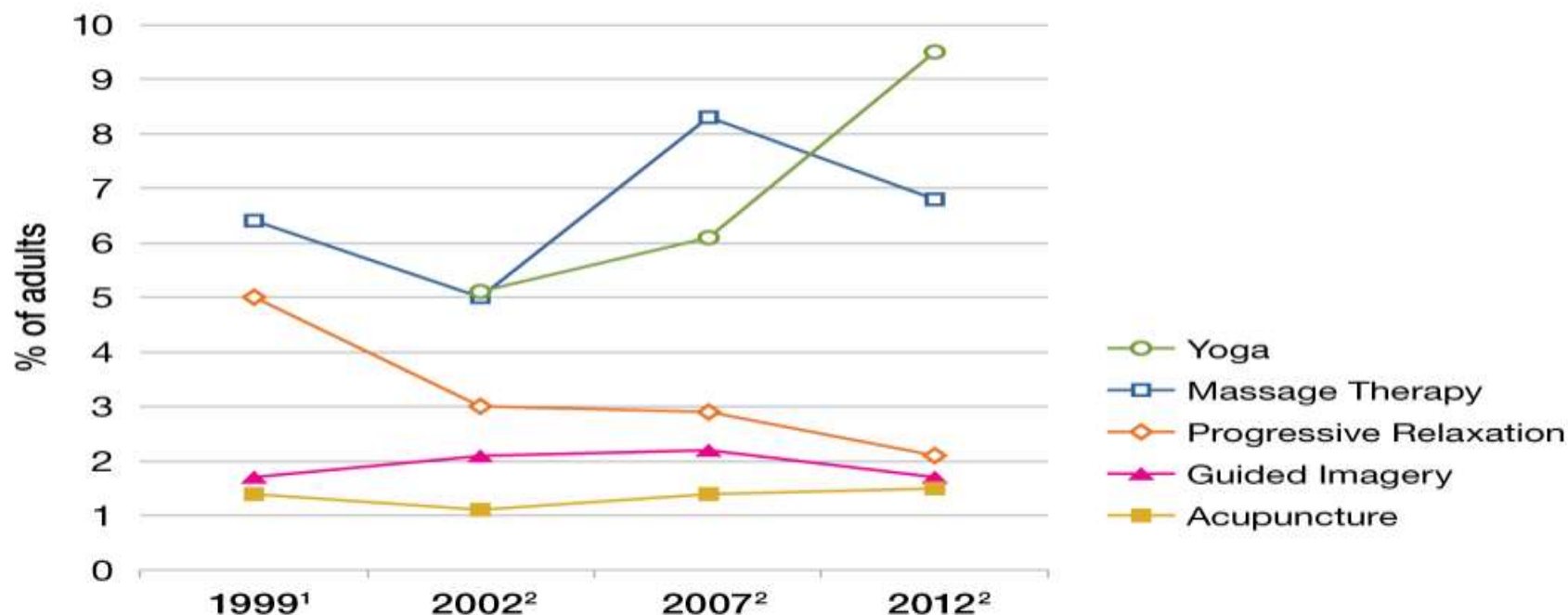
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Complementary and  
Integrative Health

[nccih.nih.gov](http://nccih.nih.gov)

## Use of Complementary Health Approaches in the U.S.

National Health Interview Survey (NHIS)

### 13-year trends for complementary approaches where questions are very similar across years



<sup>1</sup>Citation: Ni H, Simile C, Hardy AM. Utilization of complementary and alternative medicine by United States adults: Results from the 1999 National Health Interview Survey. *Med Care* 2002; 40(4):353-8.

<sup>2</sup>Citation: Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. Trends in the use of complementary health approaches among adults: United States, 2002-2012. National health statistics reports; no 79. Hyattsville, MD: National Center for Health Statistics. 2015.

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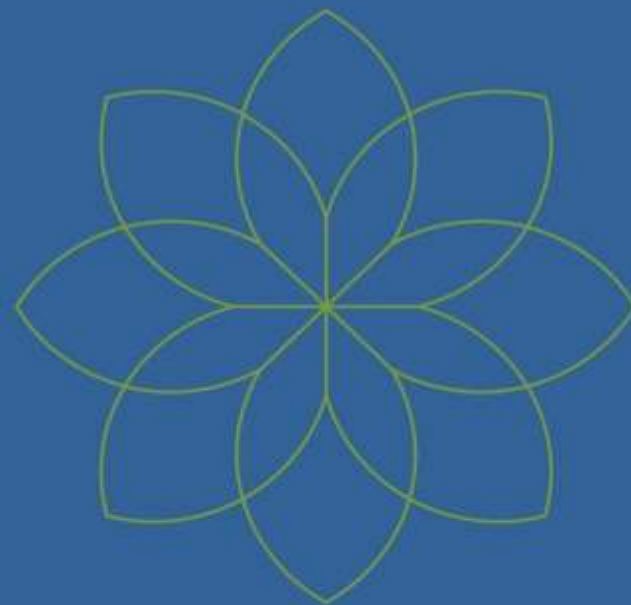
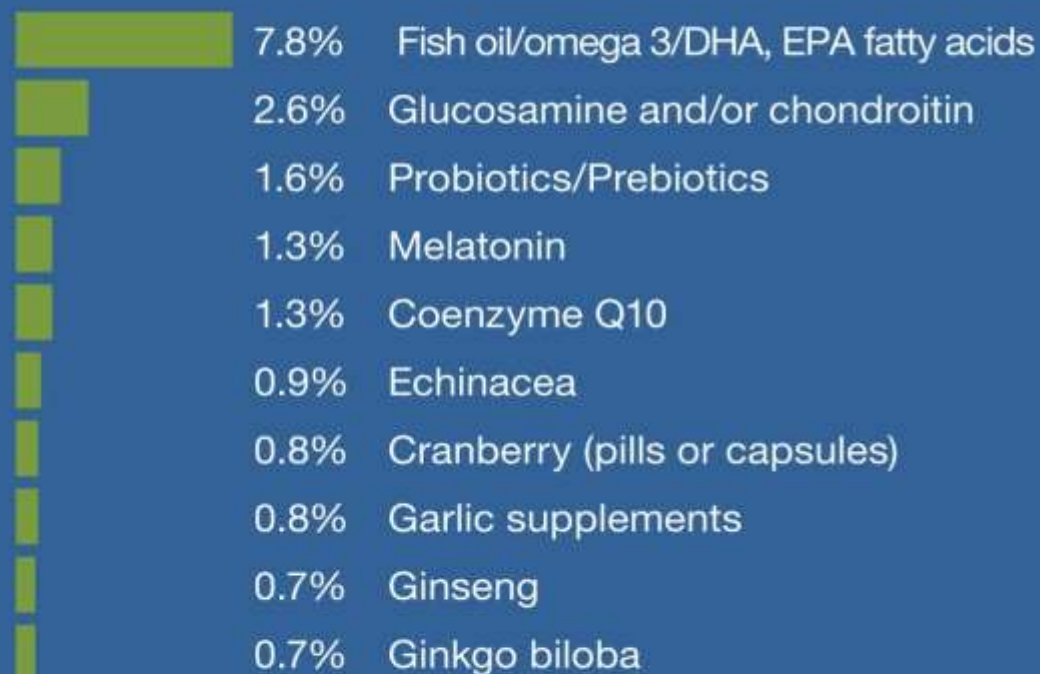




## Use of Complementary Health Approaches in the U.S.

National Health Interview Survey (NHIS)

# Most Used Natural Products by U.S. Adults



Citation: Clarke TC, Black LI, Stussman BJ, et al. Trends in the use of complementary health approaches among adults: United States, 2002-2012. National health statistics reports; no 79. Hyattsville, MD: National Center for Health Statistics. 2015.

U.S. Department of Health & Human Services • National Institutes of Health

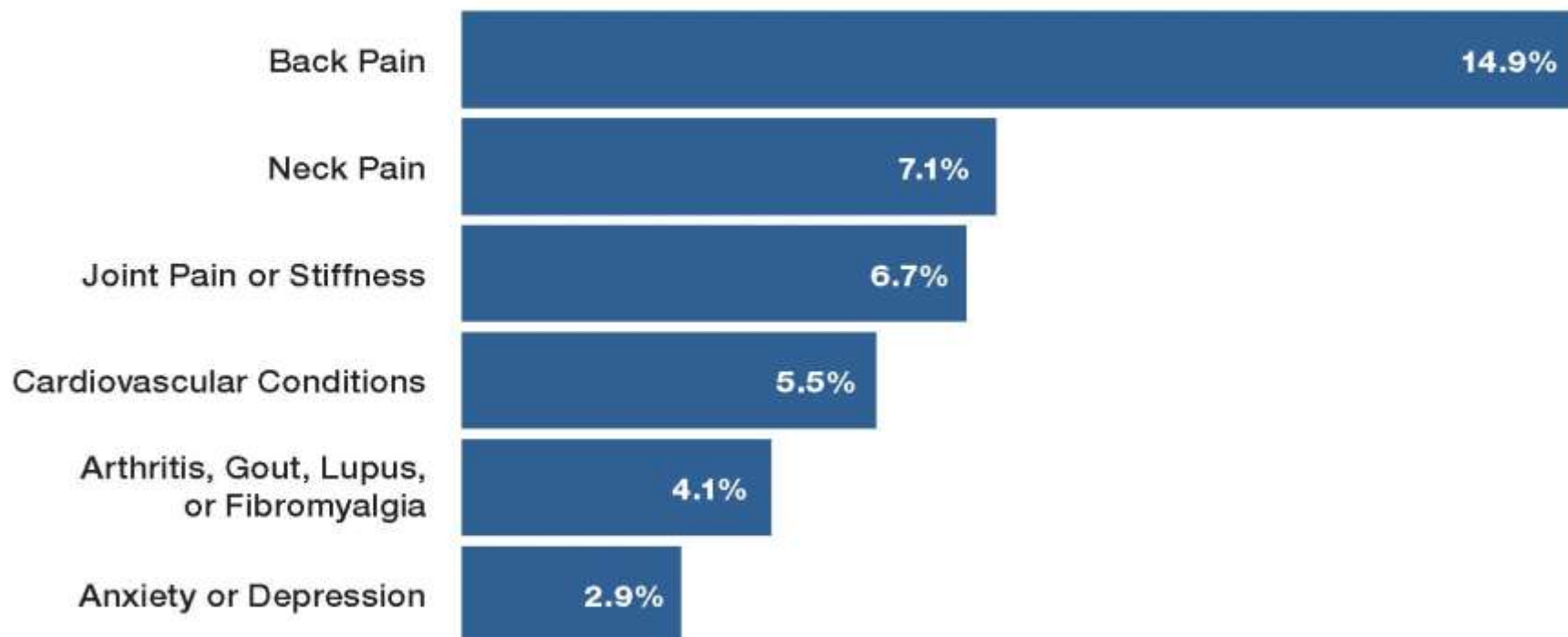


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# Diseases/conditions for which complementary health approaches are most frequently used among adults—2012

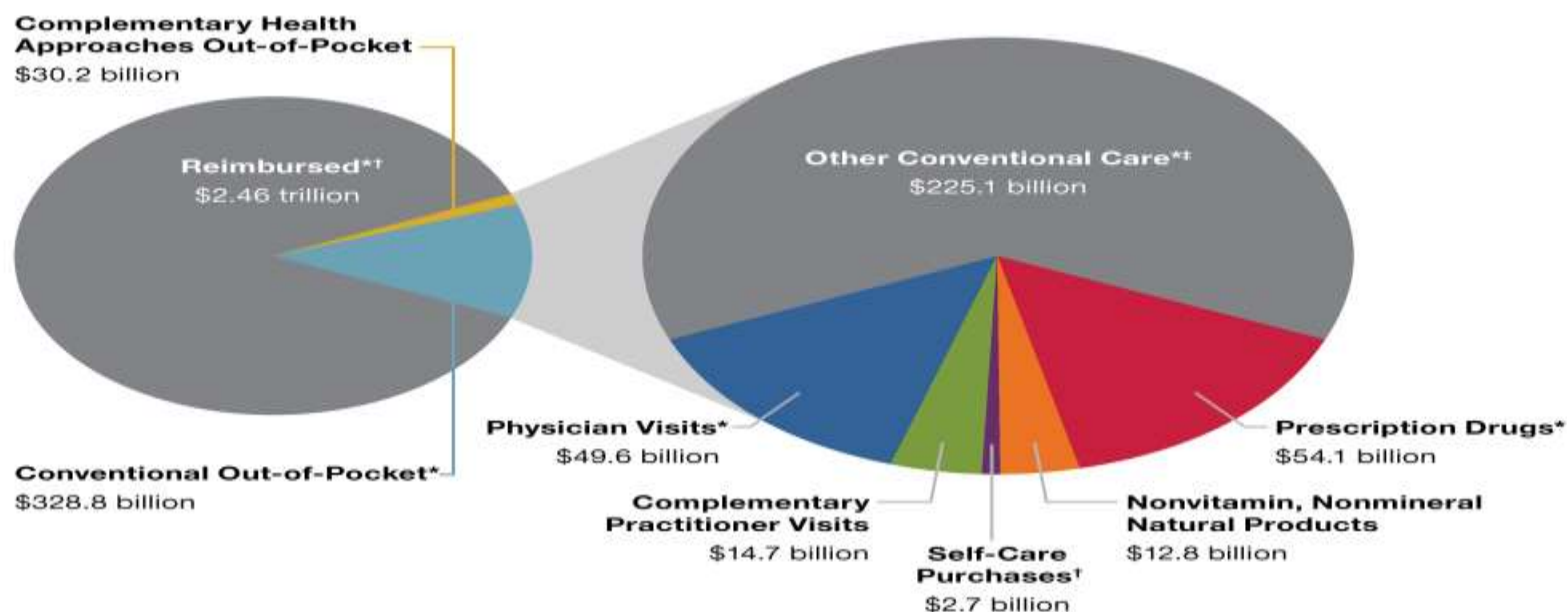


Source: Clarke TC, approaches among  
National Center for Health Statistics. 2015.



# Out-of-Pocket Spending on Complementary Health Approaches in the U.S.

Total Health Care Spending, 2012  
\$2.82 trillion



\* National Health Expenditure Data for 2012, U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services Web site, Accessed at: <https://www.cms.gov/Research-Statistics-Data-and-systems/Statistics-Trends-and-reports/NationalHealthExpendData/index.html> on March 31, 2016.

† Self-care purchases includes, for example, homeopathic medicines and self-help materials such as books or CDs related to complementary health topics.

‡ Other conventional care includes dental care, nursing homes, home health care, nondrug medical products, hospital care, and other professional services.

**Source:** Nahin RL, Barnes PM, Stussman BJ. Expenditures on complementary health approaches: United States, 2012, National Health Statistics Reports, Hyattsville, MD: National Center for Health Statistics, 2016.

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# NIH Launches TACT2

- Replication trial to assess marked benefits of chelation therapy noted in first trial
- Clinical Coordinating Center - Mount Sinai Medical Center of Florida
- Data Coordinating Center - Duke Clinical Research Institute
- Primary funding from NCCIH and NHLBI
- Major contributions from NIDDK and NIEHS
- Heavy metal testing performed by CDC



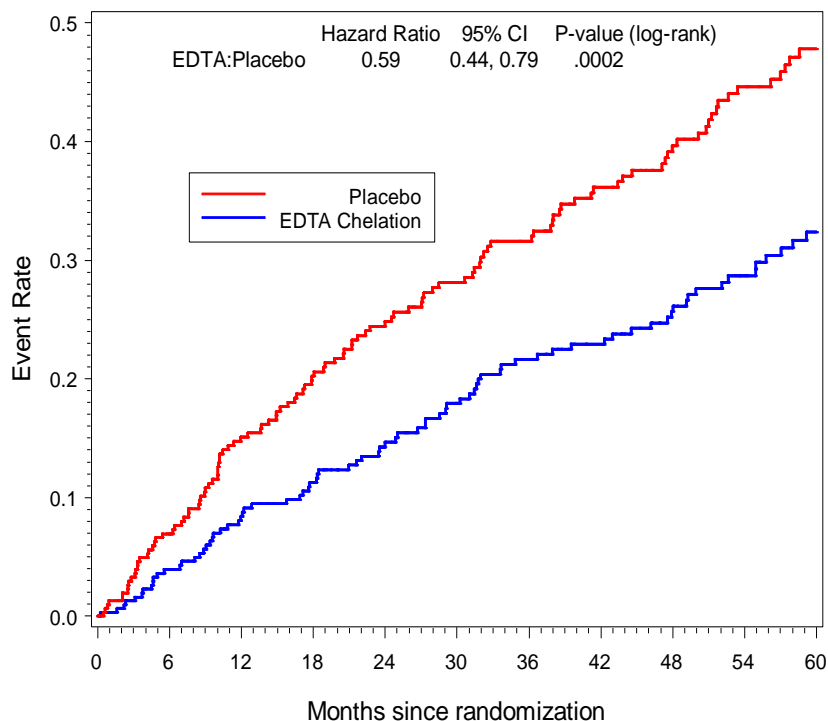


# Primary Endpoint, Diabetes vs No Diabetes

## TACT

Kaplan-Meier Estimates of the Primary Composite Endpoint  
EDTA Chelation Therapy vs. Placebo

Subset of Patients with Diabetes: Hx, Med Use or Baseline Glucose  $\geq 126$

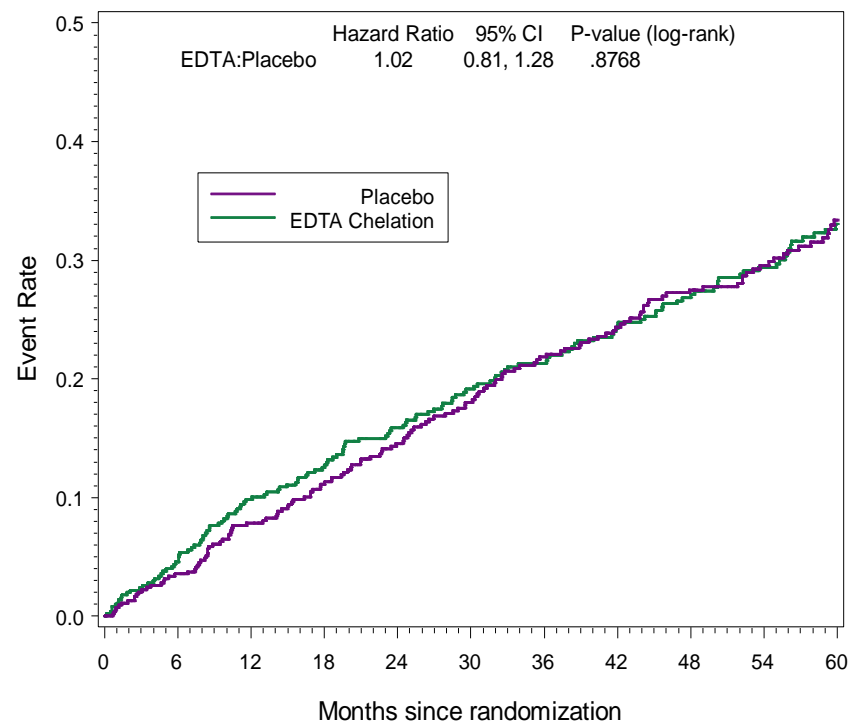


Number at Risk											
EDTA Chelation	322	286	262	243	217	198	187	177	157	126	74
Placebo	311	270	235	214	187	168	155	134	116	94	63

## TACT

Kaplan-Meier Estimates of the Primary Composite Endpoint  
EDTA Chelation Therapy vs. Placebo

Subset of Patients without Diabetes (Hx, Med Use or Baseline Glucose  $\geq 126$ )



Number at Risk											
EDTA Chelation	517	474	441	407	371	339	324	299	270	232	155
Placebo	558	506	466	424	379	347	320	295	268	228	142

Escobar E, Lamas GA, Mark DB, et al. The effect of an EDTA-based chelation regimen on patients with diabetes and prior myocardial infarction in TACT. *Circulation: Cardiovascular Quality & Outcomes*. November 19, 2013.

Lamas GA, Goertz, C, Boineau R, et al. Effect of disodium EDTA chelation regimen on cardiovascular events in patients with previous myocardial infarction. *JAMA*. March 27, 2013.

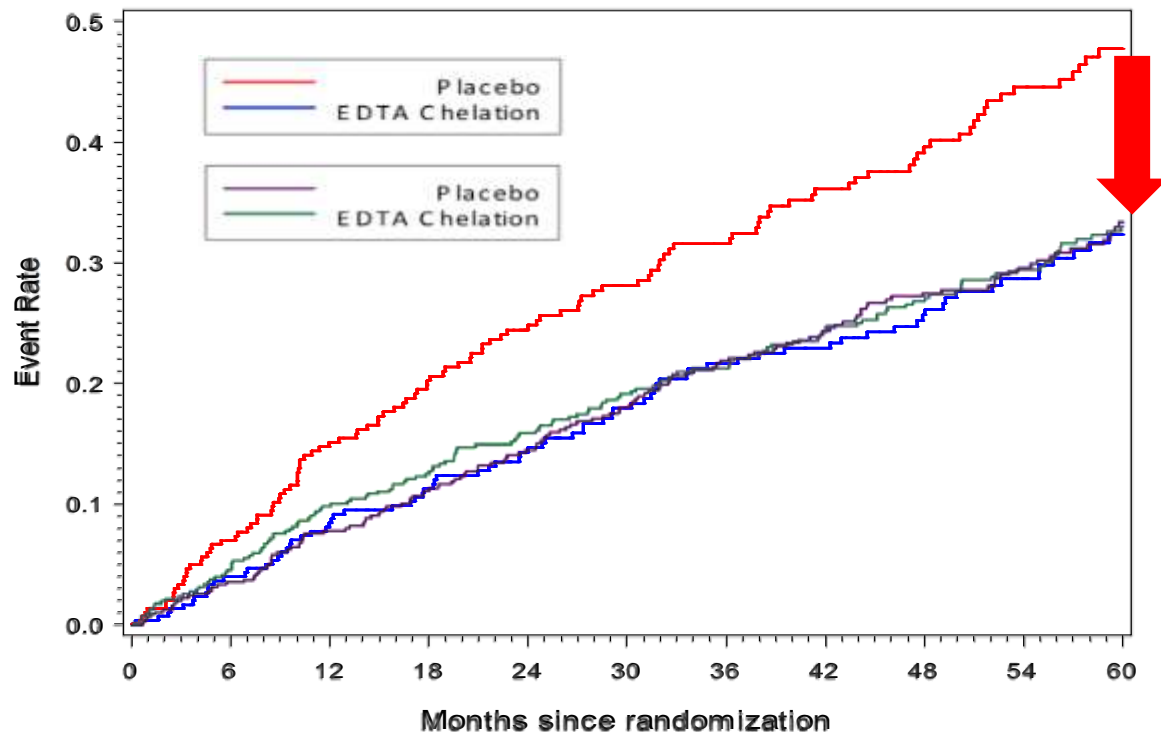


# TACT

Kaplan-Meier Estimate of the Primary Composite Endpoint

EDTA Chelation Therapy vs. Placebo

Superimposed Graphs: Subset of Patients with Diabetes & Subset of Patients without Diabetes



Source: TACT Trial

# NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program

- Supported by Office of Dietary Supplements and NCCIH
- Promote collaborative, transdisciplinary research on the safety, effectiveness, and mechanisms of action of botanical dietary supplements that have a high potential to benefit human health
  - Identify and characterize botanicals
  - Assess the bioavailability and bioactivity of chemical components of botanicals
  - Explore their mechanisms of action
  - Conduct preclinical and clinical evaluations
  - Provide a rich environment for training and career development

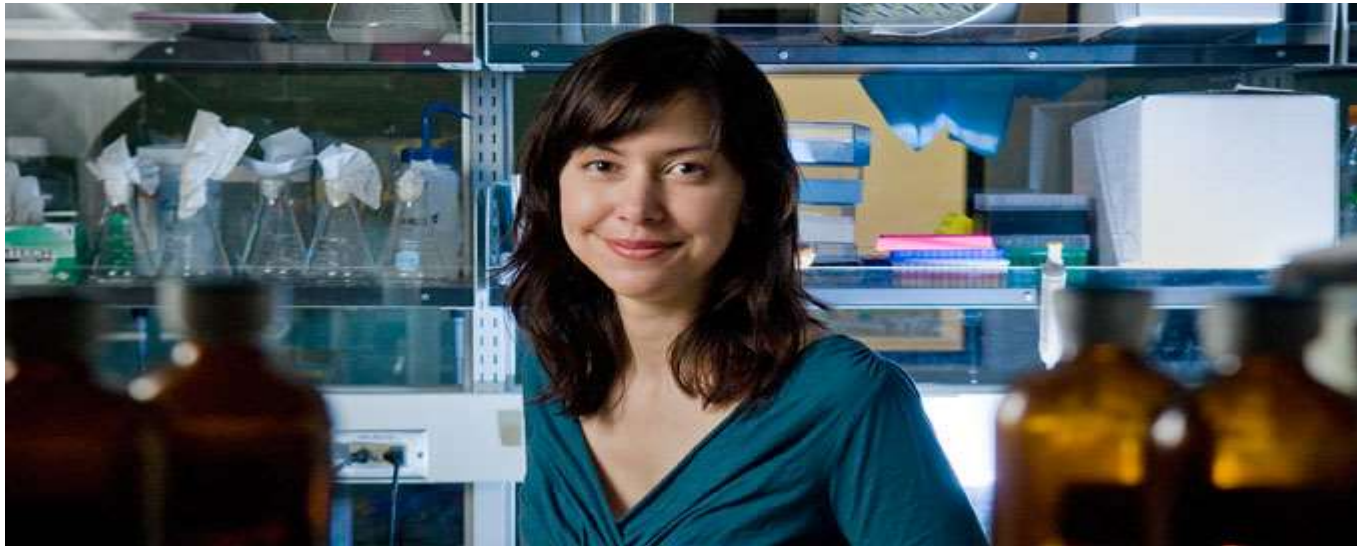


# NIH Centers for Advancing Research on Botanical and Other Natural Products (CARBON) Program

- Botanical Dietary Supplements Research Centers
  - [Dietary Botanicals in the Preservation of Cognitive and Psychological Resilience](#), Icahn School of Medicine at Mount Sinai, New York City
  - [Botanicals and Metabolic Resiliency](#), Pennington Biomedical Research Center, Louisiana State University, Baton Rouge
  - [Botanical Dietary Supplements for Women's Health](#), University of Illinois at Chicago
- Centers for Advancing Natural Products Innovation and Technology
  - [Center for High-throughput Functional Annotation of Natural Products](#), University of Texas Southwestern Medical Center, Dallas; Simon Fraser University, Burnaby, British Columbia, Canada
  - [Center for Natural Products Technologies](#), University of Illinois at Chicago



# 1DP1AT-007886 Pioneer Award SYNTHETIC BIOLOGY PLATFORMS FOR NATURAL PRODUCT DISCOVERY AND BIOSYNTHESIS



One of the many faces of NIH-supported innovation, **Stanford's Christina Smolke** is exploring how synthetic biology and microbes can be used to produce new drugs. She is a 2012 Pioneer Award winner.

**Credit:** Linda Cicero/Stanford News Service

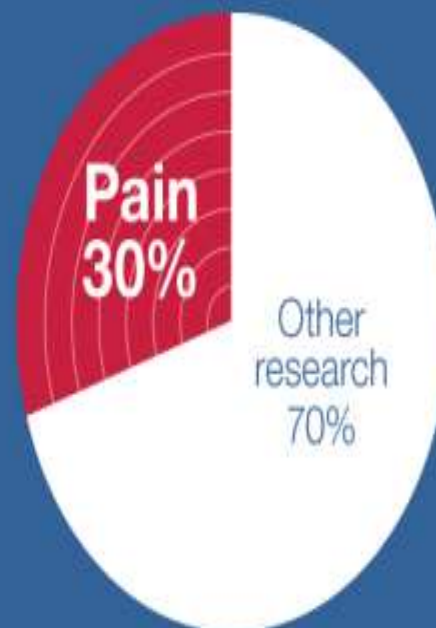




# Chronic pain: a major public health problem

## NCCIH research is tackling the problem of chronic pain:

-  We spend about 30% of our research budget on pain
-  We bring cutting-edge tools to the study of pain
-  Our research results affect guidelines for and practice of medical care
-  We are building knowledge about the placebo effect



NCCIH Research Budget





# Research Spotlight

Research

**JAMA**  
The Journal of the  
American Medical  
Association

Original Investigation

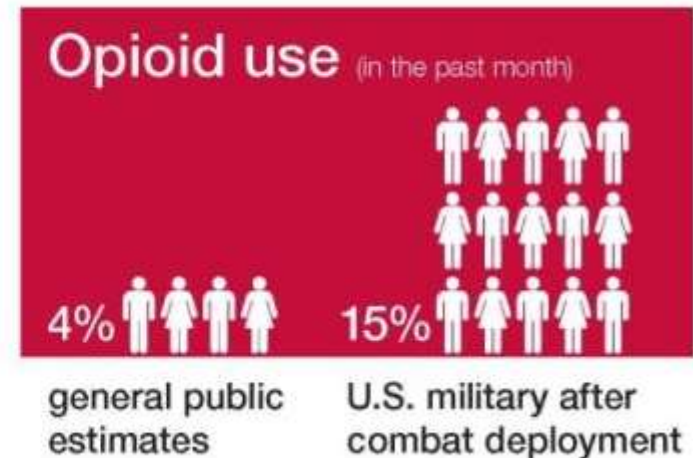
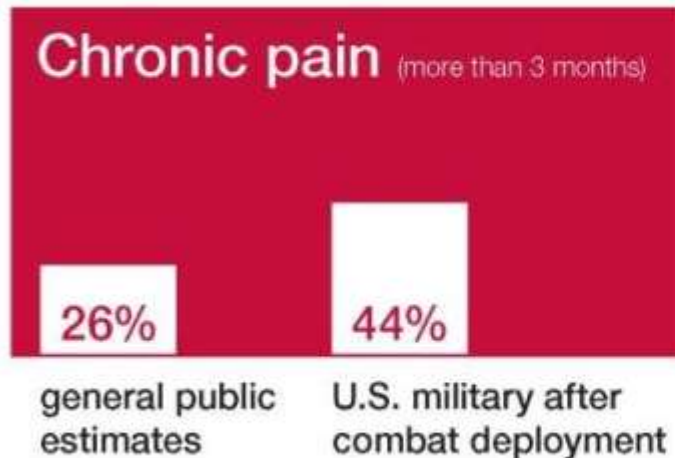
## Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain A Randomized Clinical Trial

Daniel C. Cherkin, PhD; Karen I. Sherman, PhD; Benjamin H. Balderson, PhD; Andrea L. Cook, PhD;  
Molissa L. Anderson, MS; Roma J. Hawkes, BS; Kelly E. Hansen, BS; Judith A. Turner, PhD

Full Text Available at JAMA



# Chronic Pain and Opioid Use in Soldiers After Combat Deployment



Toblin, et. al., 2011  
Toblin, et. al., 2014

# Research Spotlight

ARTICLE IN PRESS



RESEARCH

EDUCATION

TREATMENT

ADVOCACY

PUBLISHED BY



ELSEVIER

The Journal of Pain, Vol ■, No ■ (■), 2016: pp 1-8  
Available online at [www.jpain.org](http://www.jpain.org) and [www.sciencedirect.com](http://www.sciencedirect.com)

## Severe Pain in Veterans: The Effect of Age and Sex, and Comparisons With the General Population

Richard L. Nahin

*National Center for Complementary and Integrative Health, National Institutes of Health, Bethesda, Maryland.*



# Partnering on Pain Research: NIH, DoD, and VA Announce Pain Management Collaboratory Funding Initiative

- NCCIH, NINDS, NIAAA, NICHD, ORWH, NINR
- Develop the capacity to implement cost-effective, large-scale clinical research in military and veteran health care delivery organizations focusing on nonpharmacologic approaches to the management of pain and comorbid conditions. The program will:
  - Establish a Coordinating Center to provide leadership and technical expertise
  - Support the design and execution of a set of high-impact demonstration projects that will involve pragmatic clinical trials
  - Make data, tools, best practices, and resources from these and other projects available.
- Applications will be reviewed in June 2017



# What is Needed

- Mind and Body Research
  - Need for strong feasibility data and intervention refinement for developmental appropriateness
  - Larger well-controlled studies to demonstrate efficacy or effectiveness
  - Cluster randomized or group delivered interventions need special power calculation and data analysis approaches
- Natural Product Research
  - Need to demonstrate a product that has replicable biological signature to enhance rigor and reproducibility of early studies
  - Selection of dose based on optimizing biological signature
  - Product quality and consistency is important
  - Large scale well-controlled studies are needed



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# NCCIH Grants and Funding Information

- <https://nccih.nih.gov/grants>
- NCCIH Funding Opportunities
- Types of Grants and Contracts
- NCCIH Clinical Research Toolbox
- Grant Application Resources
- Awarded Grants and Contracts





https://projectreporter.nih.gov/reporter.cfm

U.S. Department of Health & Human Services



Research Portfolio Online Reporting Tools  
(RePORT)

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Fiscal Year (FY):  
Current FY is 2016

Active Projects

SELECT

### RESEARCHER AND ORGANIZATION

Principal Investigator (PI) /  
Project Leader:

(Last Name, First Name)

Use '%' for wildcard in PI names

Enter several PI/Project Leader names OR PI Profile IDs

Organization:

LOOKUP

Please enter at least 3 characters to use Lookup.

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Use '%' for wildcard

State:

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Country:

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Congressional District:

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☐ Project Abstracts

Limit Publication search to

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# NCCIH TRAINING

- <https://nccih.nih.gov/training>
- Research Training and Career Development
- Awards and Opportunities
- Institutional Training Sites
- Grant Application, Review, and Award Processes
- More Training Resources



# Description of Current Funding Opportunities

## Individual Training

- F30: dual-degree pre-doctoral (\*new)
- F31: pre-doctoral
- F32: post-doctoral

## Institutional Training

- T32: training for pre- and post-doctoral
- T35: short-term training

## Career Development

- K01: research scientist
- K08: clinician scientist
- K23: patient-oriented clinician scientist
- K99/R00: post-doctoral to independence
- K24: mid-career health-professional doctoral degree

## Administrative Supplements

- Diversity: undergraduate through faculty
- Re-Entry: post-doctoral or faculty at time of interruption
- CAM Practitioner: ND, DC, L. Ac., MT, or similar



# Take Home Message

- Integration of Complementary and Integrative Health Therapies with Conventional Practice in the Management of hard to treat conditions
- Utilize the NCCIH Research Framework for staging intervention research
- **Capitalize on Current Funding Opportunity Announcements**
- Contact NCCIH Program Staff to discuss your research concept!

<http://nccih.nih.gov/grants/contact>



# Questions?





<https://nccih.nih.gov>  
**edwardse@mail.nih.gov**

