Topics

- NCCAM’s history and mission
- Data on CAM use in America
- Achievements of ten years of NCCAM research – and lessons learned
  - in mind body research
  - in natural product research
- Challenges of CAM research
- N of one trials
Legislative language

“The general purposes of the National Center for Complementary and Alternative Medicine (NCCAM) are the conduct and support of basic and applied research…research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciplines and systems.”

P.L. 105-277

October 1998
NCCAM: Mission

- Explore complementary and alternative healing practices using rigorous scientific methods and develop the evidence base for safety and efficacy of CAM approaches.
- Support the development of trained researchers.
- Disseminate authoritative information to the public and professionals.
NCCAM’s Budget: 0.4% of the NIH Total

- $30 Billion: Rest of NIH
- $125 Million: NCCAM
NCCAM’s Appropriations History
NCCAM is a TEAM PLAYER

Examples

- Ginkgo Evaluation of Memory Study (GEMS) – NCCAM, NIA, NINDS, NHLBI, NIH ODS
- Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) – NCCAM, NIAMS
- St. John's Wort for Major Depression of Moderate Severity – NCCAM, NIMH, NIH ODS
- National Health Interview Survey – NCCAM and CDC
- Systematic evidence-based reviews – NCCAM and AHRQ
NHIS CAM Modules: 2002 and 2007

- 2007 Survey: 36 different CAM therapies for 81 different diseases/conditions
- Sample of 23,000 adults
The 2007 NHIS collected CAM information on a subset of 23,393 adults and 9,417 children. This sample is representative of the civilian, non-institutionalized U.S. population.
NHIS CAM Module Survey: Demographics of CAM Use, 2007

- Approx 40% of American public use CAM, consistent with earlier surveys
- 1 in 9 U.S. children use CAM
- Widespread in all demographic groups
- Women > men
- West > Midwest > Northeast > South
- Greater use in people with higher education levels
Adult Use of Selected CAM Therapies: United States, 2007

- Natural products: 38.8 million
- Deep breathing: 28.9 million
- Meditation: 20.1 million
- Manipulative Rx: 18.3 million
- Massage: 16.7 million
- Yoga: 16.0 million
- Special diets: 13.2 million
- Relaxation: 10.6 million
- Imagery: 6.2 million
- Acupuncture: 3.0 million

Barnes et al., 2008
Adult Use of Selected CAM Therapies: 2002 vs. 2007

Barnes et al. 2004, 2008
Use of Selected CAM Therapies: Adults vs. Children

Barnes et al., 2008
Why do people turn to complementary or alternative medicine?

To promote health and wellness

To treat specific health conditions and symptoms

(Mostly as an adjunct to conventional care)
Adult Use of CAM for Selected Health Conditions

- Back pain: 14.3 million
- Neck pain: 5 million
- Joint pain: 1.8 million
- Arthritis: 1.8 million
- Anxiety: 1.8 million
- Cholesterol: 1.8 million
- Colds: 1.8 million
- Other musc: 1.8 million
- Headache: 1.8 million
- Insomnia: 1.8 million

Barnes et al., 2008
Children’s Use of CAM for Selected Diseases

- .7 million
- .2 million
- .1 million

Barnes et al., 2008
Top Herbal Medicines and Other NVNMDS:

NVNMDS = non-vitamin/non-mineral dietary supplements

- Echinacea
- Ginseng
- Ginkgo biloba
- Garlic Supplements
- Glucosamine
- St. John’s Wort
- Peppermint
- Fish Oil/Omega 3
- Ginger Supplements
- Soy Supplements

% of adults using NVNMDS

2002

2007
What do the numbers tell us?

- Complementary and alternative health practices, especially natural products, meditation, massage, manipulative therapies, and yoga are widely used by the American public, including children.
- Chronic pain, especially back pain, is the most common reason.
- Media coverage and public interest is strong.
- NIH Research influences the public.
NCCAM: Our Research Expertise

Studying Real World Health Practices

CHALLENGES

- Need to partner with disease experts
- Need careful product characterization
- Need strong preliminary data
Preliminary data needed for major RCT’s of CAM interventions:

- Strong biological hypothesis
- Well described intervention
- ‘Proof of concept’ preliminary clinical data
- Good chemistry of any natural products (ADME) and marker(s) to verify biological effect *in vivo*
- Maximally sensitive outcome measures and trial design
NCCAM: The CAM Research Paradigm

- How does it work?
- Do we have the tools to study it in people?
- What are the specific effects?
- Is it better treatment?

Basic Science
 Translational Research
 Efficacy Studies
 Effectiveness Research
Cheat death.

The antioxidant power of pomegranate juice.
NCCAM Research: Areas of promise in mind and body CAM approaches

- Benefits of mindfulness mediation for stress reduction and quality of life - for examples for Alzheimer care givers

- Benefits of yoga and Tai chi for balance and avoiding falls in elderly people

- Insight into of central mechanisms of reassurance and expectancy

- Contribution of acupuncture and other mind and body practices to pain management
NCCAM: Achievements in natural product research

- Implementation, in partnership with other IC’s, of 6 major high-quality RCTs of widely used natural products

- Rigorous processes to assess quality and consistency of herbal and other natural products used in NCCAM research
  (PIWG: Product Integrity Working Group)
Autism Spectrum Disorders: CAM for Symptom Management

- Numerous provider and parent reports suggest that certain CAM practices show promise to contribute to symptom management.
- Limited scientific evidence.
- Children’s safety paramount.
NCCAM: Expertise in studying untested therapies already in use by the public

- CAM research, as a scientific discipline, has advanced dramatically in the last ten years
- NCCAM has established a CAM research enterprise at the Nation’s premier biomedical research institutions
- Partnerships with CAM practitioners are critical to our efforts
- NCCAM has special expertise in applying rigorous scientific inquiry to health and wellness promotion practices already in use
- Experience has taught us that the evidence base for a particular therapy’s use must be developed incrementally
First Steps: The road from anecdote to proven efficacy

“The plural of anecdote is not evidence.”  S. Straus

- Therapies are in current use without scientific proof of safety, efficacy, or effectiveness

- How do we find out if they work?
  - Investigator-initiated research
  - Collaborations with NIH Institutes and Centers and other Federal agencies with specific expertise
Study of Omega-3 Fatty Acids for Children with Autism Spectrum Disorders

- Double-blind, placebo-controlled, RCT
- Comparing omega-3 fatty acids with placebo to assess effects on
  - Aggression and irritability
  - Functional ability

PI: Sherie Novotny, M.D.
Robert Wood Johnson Medical School
n-of-1 Trials

- Randomized, double-blind, placebo-controlled crossover comparison trials in a single patient
- Patient-centered approach to testing therapeutic efficacy for symptom management
- Useful in patients with chronic diseases or conditions to test short term effects
**n-of-1 Controlled Trials**

- What are they?
- How are they designed?
- Could they be useful in determining the role of CAM in the management of symptoms associated with Autism Spectrum Disorders?
**n-of-1 Trials: Role in testing CAM therapies for Autism Spectrum Disorders?**

- Develops “proof of concept” data required before larger-scale studies are conducted.
- Helps determine if, when (e.g., response variations), and how a therapy might be used effectively for symptom management.
- Encourages provider, parent, patient partnerships.
CAM and Autism

- Complementary and alternative health approaches have substantial promise to contribute to practical management of symptoms and burden of ASD on patients and their families.

- NCCAM welcomes opportunity to partner in trans-NIH Autism Coordinating Committee.
National Center for Complementary and Alternative Medicine

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