



SamueliInstitute.org

Moving Toward More Meaningful Evidence for Whole Person Care:

*The perspective of a researcher
(who is trying to be more patient-centered)*

Jon Tilburt, MD

Mayo Clinic

Samueli Institute

Patients at the Crossroads: RECONCILING PATIENT-CENTERED CARE,
EVIDENCE-BASED PRACTICE, AND INTEGRATIVE MEDICINE

Nov. 8-9, Alexandria, Virginia

Arthur Frank

“[We] would not be speaking of ‘patient centered care’ at all if there were not deep professional institutional reasons for being centered on concerns other than patients.”

Jon Tilburt

- Assertion: There have been deep professional institutional reasons for biomedical research being centered on concerns other than patients.
- Question: What would it take to make evidence from research more meaningful for whole person care?

Disclosures

- None
- The views expressed are my own and do not represent positions or policies of Mayo Clinic

Definitions

- Patient-Centered Care
- Evidence Based Medicine
- Integrative Medicine

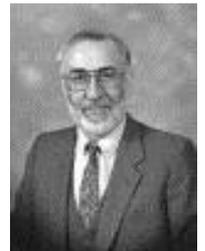
Patient Centered Care

“Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.”

- IOM

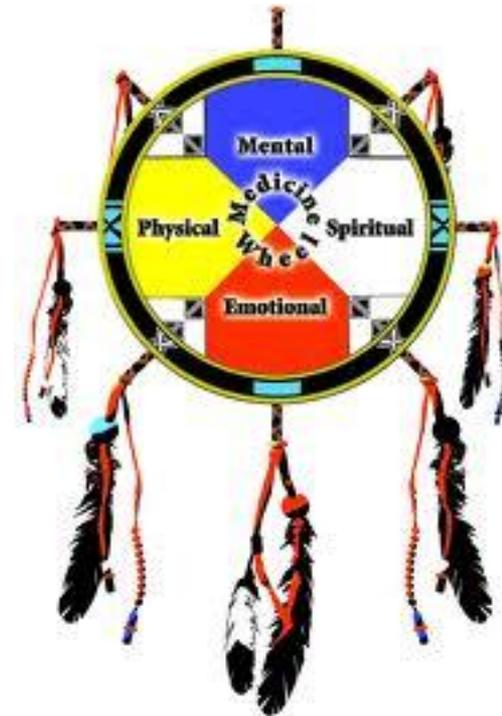
Evidence Based Medicine (EBM)

“ Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. ”



Integrative Medicine

“Integrative Medicine is the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing.”



The Basic Logic

- We say “care” should be patient-centered
- Increasingly, “care” = discrete, researched “interventions”
- How we study “care interventions” reflects a worldview
- Patients don’t necessarily share the assumptions and priorities of the biomedical worldview
- Q: Must patients share the biomedical worldview?
- Q: If not, should research assumptions adapt to patient assumptions? If so, how?
- Does research need to change, so that the care derived from research can be more centered on patient concerns?

Lack of Meaningful Research

- Most of biomedical science has minimal or delayed impact on medical care
- Lack of impact may related to
 - what questions, methods, & evidence are valued in research
 - Whose voice gets included in setting the research agenda

Meaningful Biomedical Research

- Address high impact questions
- Is relevant to patients & doctors
 - For day-to-day health problems
- Whose evidence is
 - Accessible
 - Clear
 - Meaningful (measures important things)
 - Constantly updated
 - Available when it is needed
- This would be “Patient-centered” research

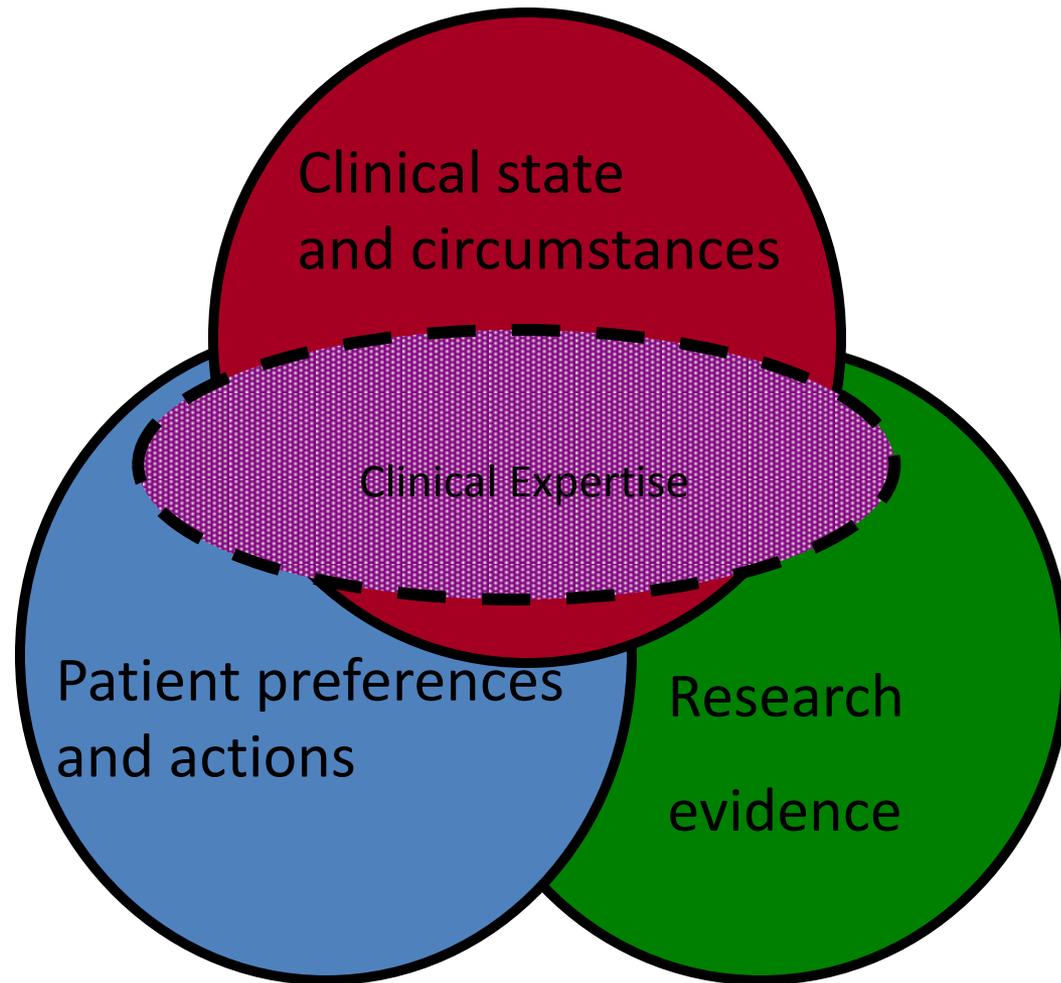
The Status of Biomedical Research

- Increasingly “care” = discrete, researched “interventions”
- Research & evidence are currently “other-centered”
 - “other” than the patient
 - Economic/bureaucratic interests
- Questions, methods, & evidence serving the purposes of others, not patients
 - Scientist/regulator-centered
 - Focused on
 - causal attribution
 - Internal validity (reducing bias)
- Reflect the assumptions of a biomedical worldview

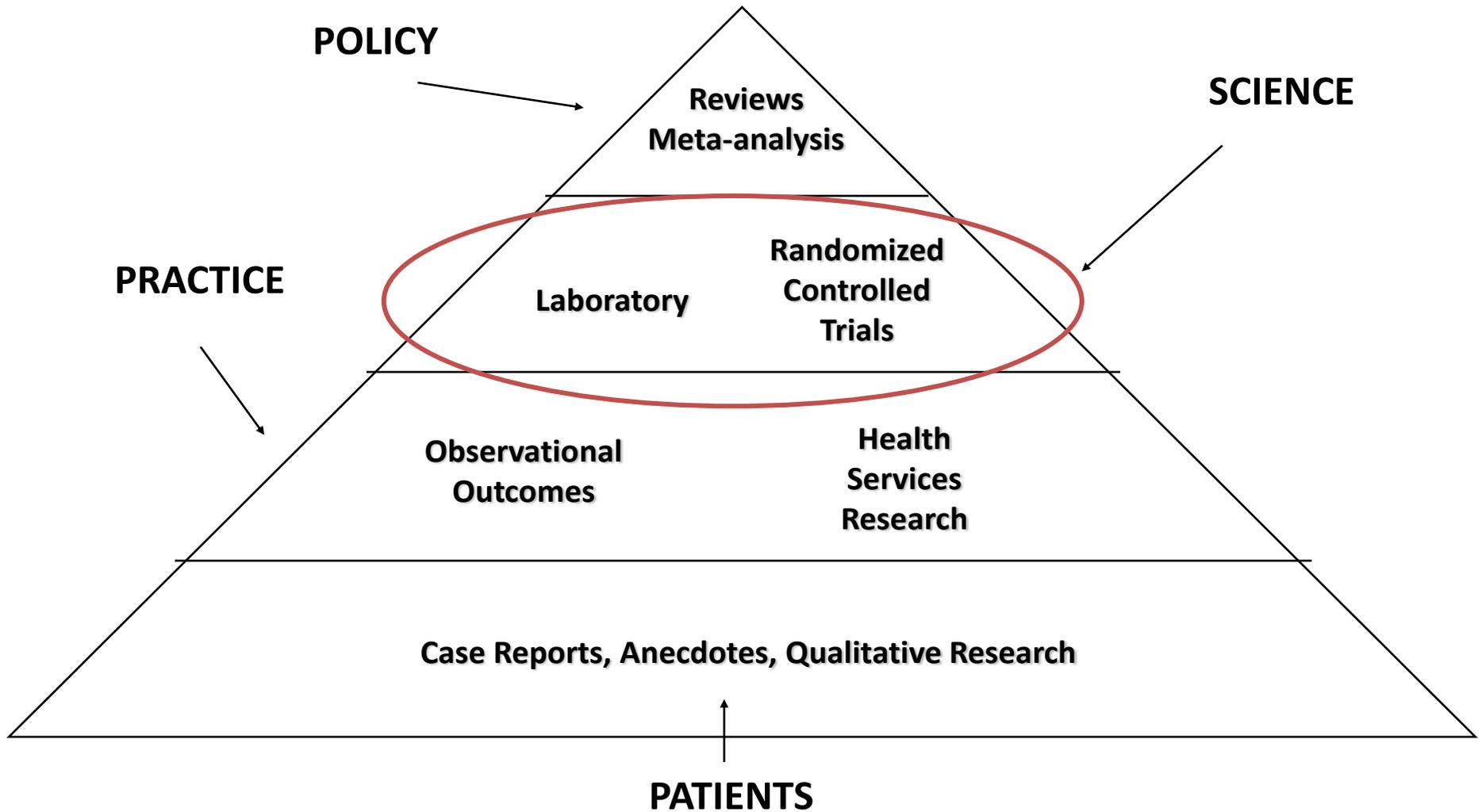
The Biomedical Worldview

- Facts: Objective realities
- Reality: Mind/Body Duality
- Knowledge comes from science
- Medicine's Objective: Focus on "fixing" the body using the objective knowledge of biomedical science
- Methods focus: determine cause-effect relationships of discrete "fixes"
- Evidence-based medicine
 - "efficacy" focused

Evidence Based Medicine



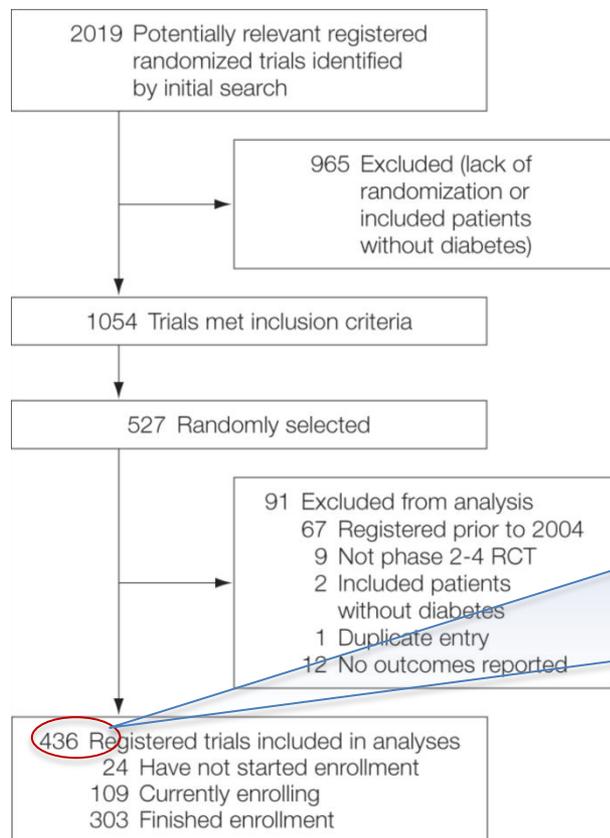
EBM Evidence Hierarchy



To “know” in the biomedical worldview means that there is RCT evidence of specific effect of a discrete intervention on an objectively measurable outcome . . . regardless of whether those outcomes are important to patients

Patient-Important Outcomes in Diabetes Trials

JAMA. 2008;299(21):2543-2549. doi:10.1001/jama.299.21.2543



Primary Outcomes

- 61% surrogate outcomes
- 16% physiology outcome
- 18% patient-important

Only 46% reported any patient-important outcome

Implicit Biomedical/EBM Assumptions

It is more valuable to be able to . . .

- Definitely decipher the causal role of a discrete intervention
 - on a cleanly measured objective surrogate outcome
 - with minimal possibility of bias (efficacy)
 - in a highly controlled setting
- Than it is to identify potentially beneficial interventions
 - that *may* have benefit on objective or subjective outcomes
 - in uncontrolled settings

These assumptions are a kind of faith commitment

- Not empirically-verifiable value judgments
- Reflect and are derived from the Biomedical Worldview

If research questions or outcome measures used are not important to patients, & the methods do not fit patient questions the social value of the research is significantly diminished.

The NEW ENGLAND JOURNAL of MEDICINE

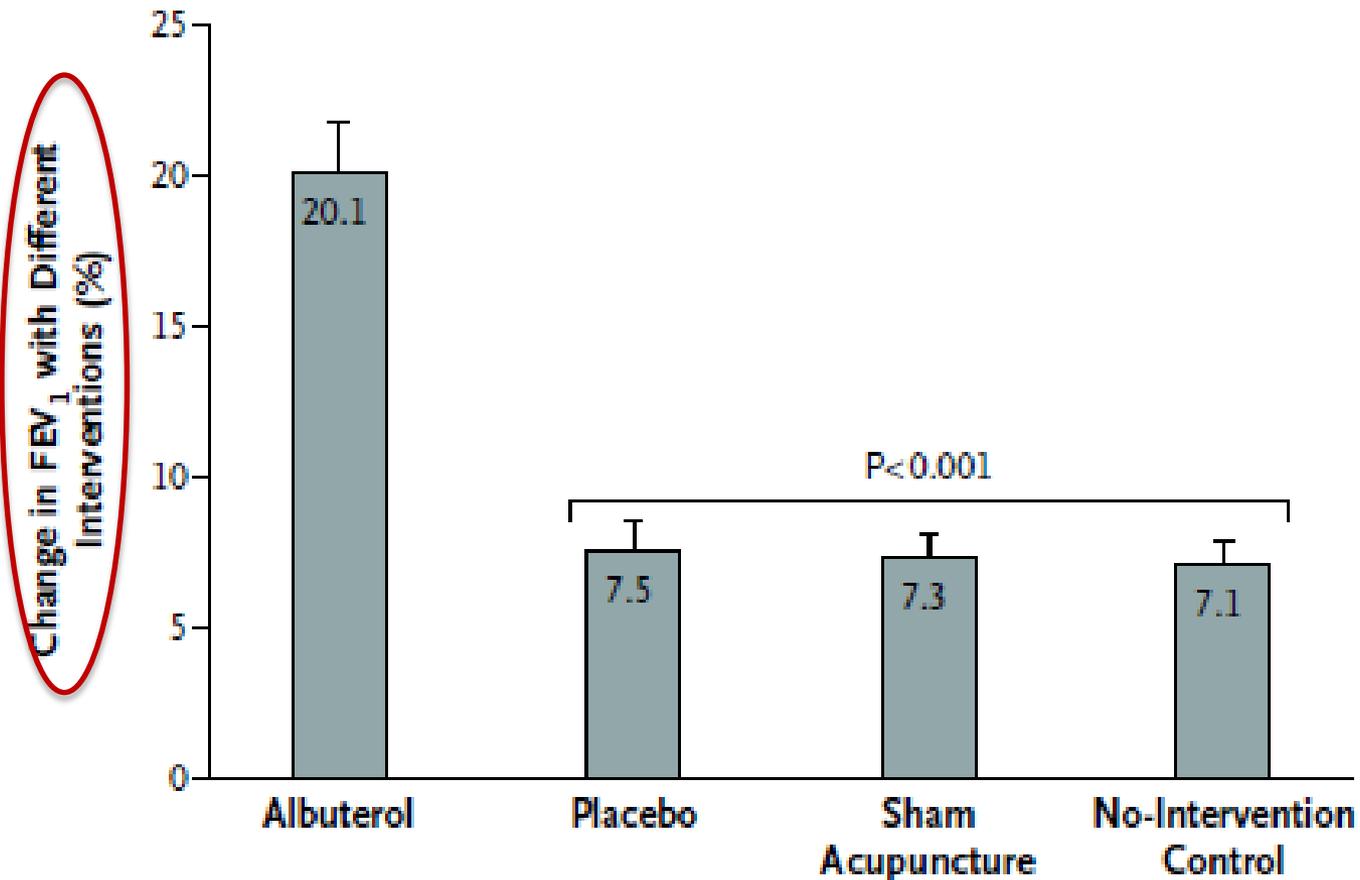
ORIGINAL ARTICLE

Active Albuterol or Placebo, Sham Acupuncture, or No Intervention in Asthma

Michael E. Wechsler, M.D., John M. Kelley, Ph.D., Ingrid O.E. Boyd, M.P.H.,
Stefanie Dutile, B.S., Gautham Marigowda, M.B., Irving Kirsch, Ph.D.,
Elliot Israel, M.D., and Ted J. Kaptchuk

N Engl J Med 2011;365:119-26.

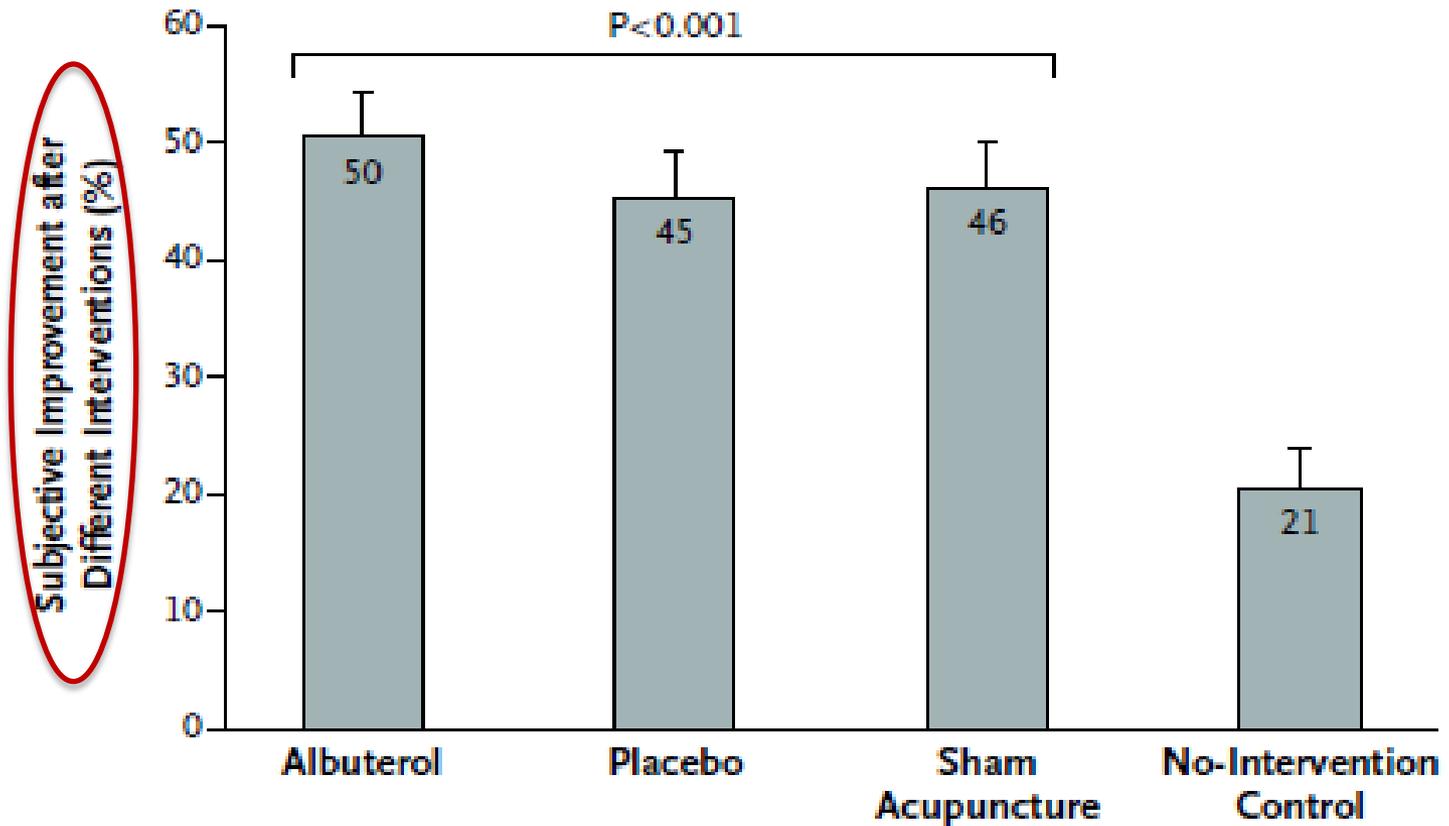
49 pts randomized, cross-over block design



Percent Change in Maximum Forced Expiratory Volume in 1 Second (FEV₁) with Each of the Four Interventions.

Asthma Therapy

What is the most effective Rx?



Percent Change in Subjective Improvement with Each of the Four Interventions.

Is Sham Acupuncture Effective in Asthma?

Different Conclusions

- Biomedical conclusion: sham acupuncture is not objectively better
- Patient-conclusions: sham acupuncture helps patients feel better even if it doesn't help the numbers

How Can We Make Research
More Patient Centered?

Strategies

- Adjust what counts as
 - rigorous methods
 - important outcomes
 - meaningful benefit
 - solid evidence
- Include different voices in crafting questions
- Design interventions with end-users in mind

What Counts as Rigorous Methods

- Integrative medicine modalities
 - Bundled, difficult to define, individualized, depend on relationship effects
- Need full range of methods
 - Flexible experimental designs
 - More observational methods
 - Clever analytic strategies

What Counts as an Important Outcome

FROM

- biological surrogate markers

TO

- Patient-important outcomes
 - Death
 - Disability
 - Quality of Life (Patient-reported outcomes)

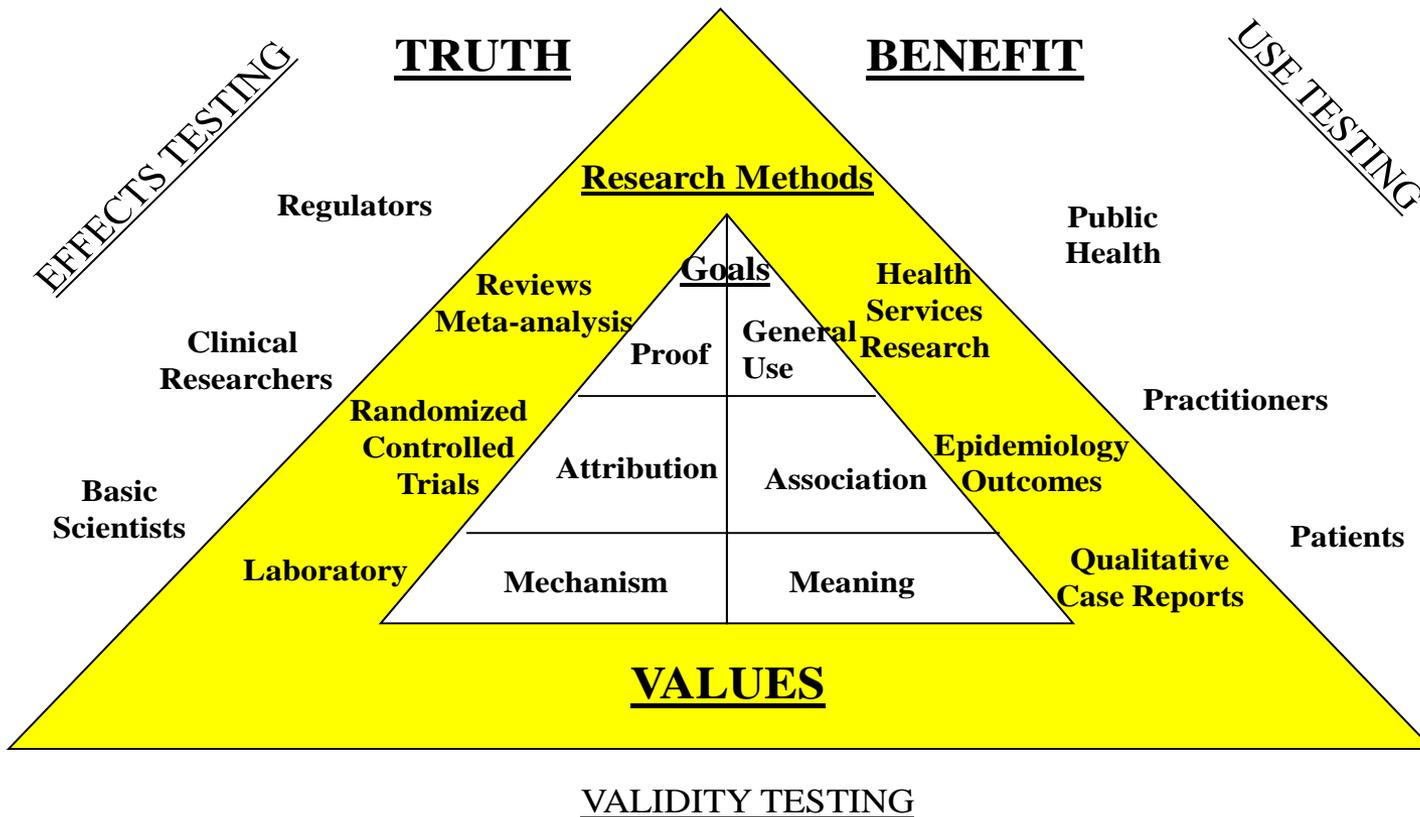
What Counts as Meaningful Benefit

A Meaning Response as Meaningful Evidence

- Warm relationship adds further therapeutic response to sham therapy alone
 - Kaptchuk et al., *BMJ* 336:999, 2008
- Placebo effects can be preserved even with disclosure
 - Kaptchuk et al., *PLoS ONE* 5, 2010

What Counts as Solid Evidence

The Evidence House



Strategies

- Adjust what counts as
 - rigorous methods
 - important outcomes
 - meaningful benefit
 - solid evidence
- Include different voices in crafting questions
- Design interventions with end-users in mind

Different voices in crafting questions

- Regulators
- Industry
- Basic scientists preoccupied by mechanism
- Taxpayers
- Insurance companies
- Clinicians & patients

Designing Interventions

- **Human-centered**

Drive decisions from human need, but never assume you have reached a point of complete understanding.

- **Intuitive**

Constantly challenge your assumptions about what is true and what is possible. If you are about to dismiss an idea, ask yourself... why not?

- **Innovative**

Identify untapped, underappreciated resources and move them from a state of low productivity to a state of high productivity.

- **Systemic**

Avoid wasting energy trying to eradicate a problem when you can seek solutions that make it obsolete.

- **Iterative**

Create to learn through low-fidelity prototyping and refinement in the real world before making a full scale investment. Always challenge yourself to come up with multiple solutions before optimizing one.

What would it take to make
evidence from research more
meaningful for whole person care?

Toward Patient-Centered Research

- Acknowledge that there is a problem
- Pay attention to assumptions
- Be willing to learn
- Remind others what they already know
- Implement practical strategies
- Create incentives for innovative methods & questions that reflect a robustly patient-centered mentality

Acknowledgments

- Center for the Science of Healthcare Delivery
- Knowledge & Evaluation Research Unit
- Biomedical Ethics Research Unit
- Program in Complementary & Integrative Medicine
- Center for Innovation



Thank You

Tilburt.jon@mayo.edu

Backup Slides

Educational Objectives

Participants will be able to . . .

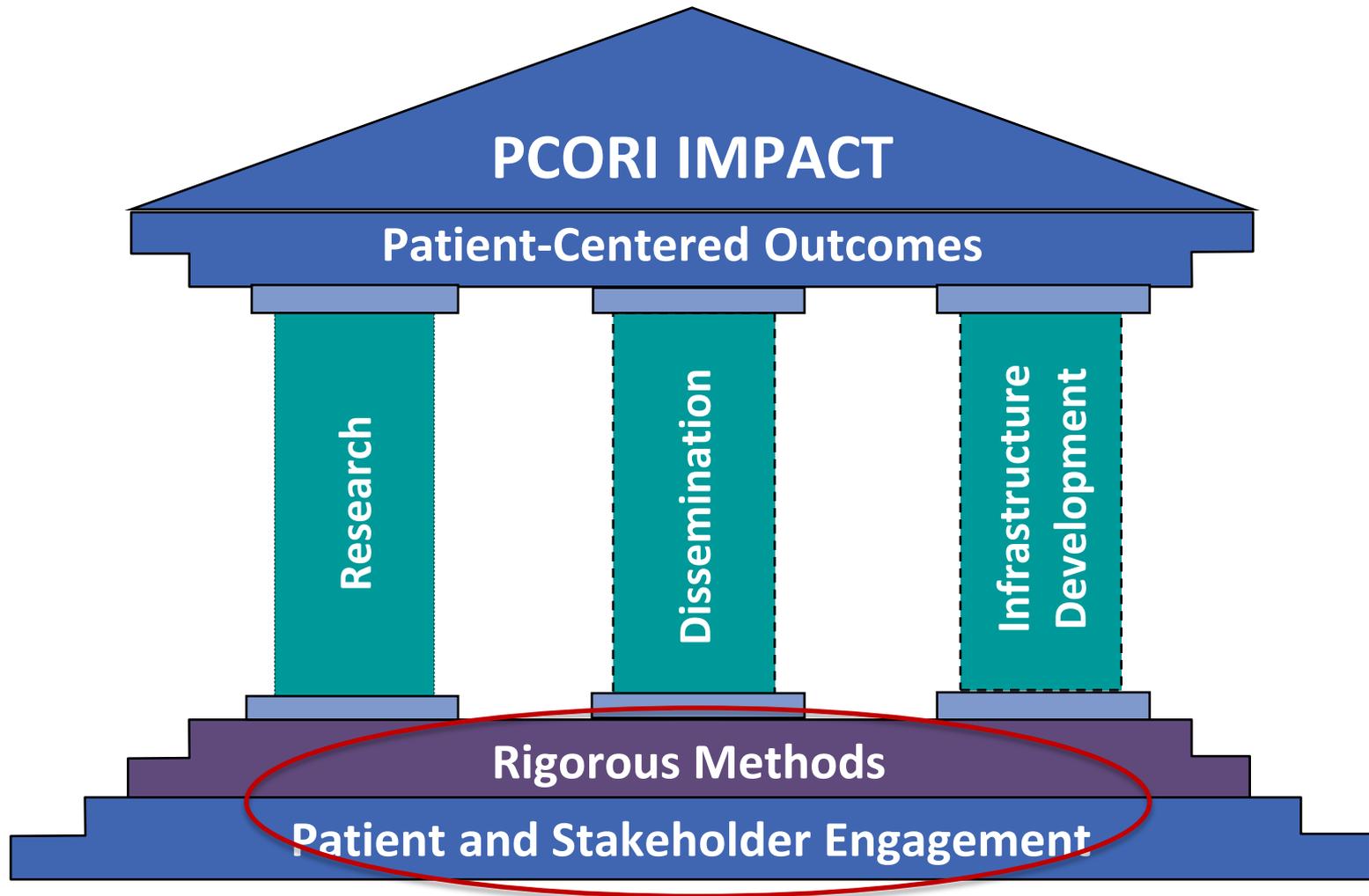
- List the barriers to meaningful, patient-centered research production
- Describe the ways in which the biomedical research paradigm may not be patient-centered
- Identify implications of these barriers and paradigms for integrated healthcare research
- Name at least 3 key strategies for making research & evidence more patient-centered

Are we making any progress?

Patient Centered Outcomes Research Institute (PCORI)

- Mission: “[PCORI] helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.”

PCORI Foundational Pillars



IOM Recommendations for CER

1. Head to Head Comparisons
2. Broad range of topics.
tests, treatments, strategies for delivering healthcare
3. Focus on **patient-centered decision-making**
tailor the test or treatment to the specific characteristics of the patient.
4. Stakeholders: patients, clinicians, purchasers, and policy makers.
5. **Study populations representative of clinical practice**

What Makes Research Ethical

1. ***Social Value***
2. *Scientific Validity*
3. *Fair Subject Selection*
4. *Favorable Risk-Benefit Ratio*
5. *Independent Review*
6. *Informed Consent*
7. *Respect for subjects*

“Clinical research must lead to improvements in health or advancement in generalizable knowledge.”

Investigators must consider how the research will improve health of:

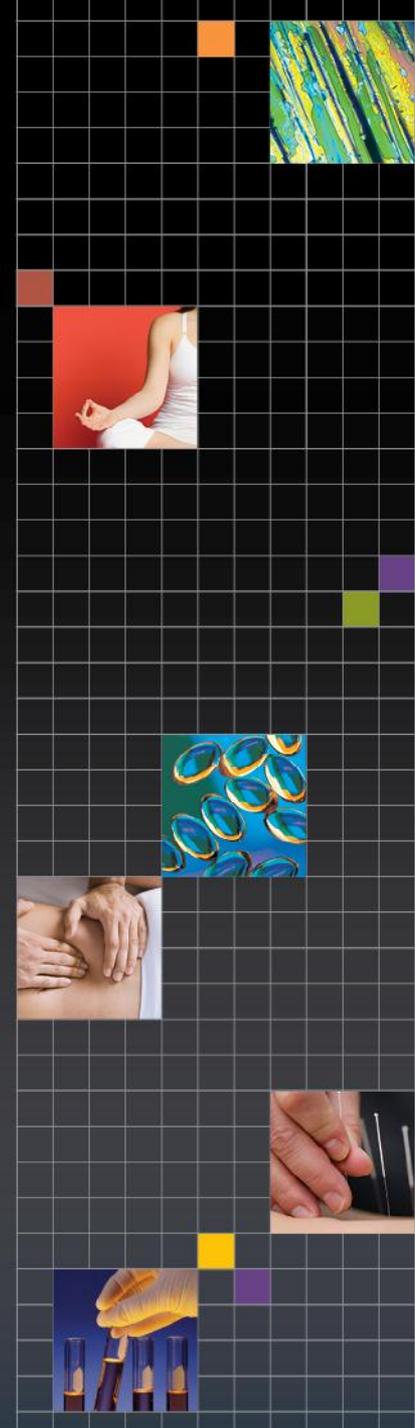
- Participants in the research
- Community in which research is conducted
- World

What Counts as Rigorous Methods

- N-of-1 trials
- Preference RCTs
- Observational & cohort studies
- Case control studies
- Attribute-Treatment Interaction Analysis
- Qualitative Methods
- Bundled interventions
 - Multi-modality
 - Schools of thought

Putting the Patient in the Center in Research on Complementary and Integrative Health

November 9, 2012
Dr. Josephine Briggs
Director, NCCAM



HEALTH CARE MAY 18, 2010

Patient Satisfaction Declines at Hospitals

ARTICLE

COMMENTS

By SARAH MORGAN

A

A

Consumers have gotten happier with their cable TV providers and their cellphone companies, but they're not so pleased with their local hospitals, according to the latest American Customer Satisfaction Index. The index, released Tuesday, offers a quarterly look at customer satisfaction for major businesses, including cable and satellite television, wireless and fixed-line phone services, utilities, computer software and health care.

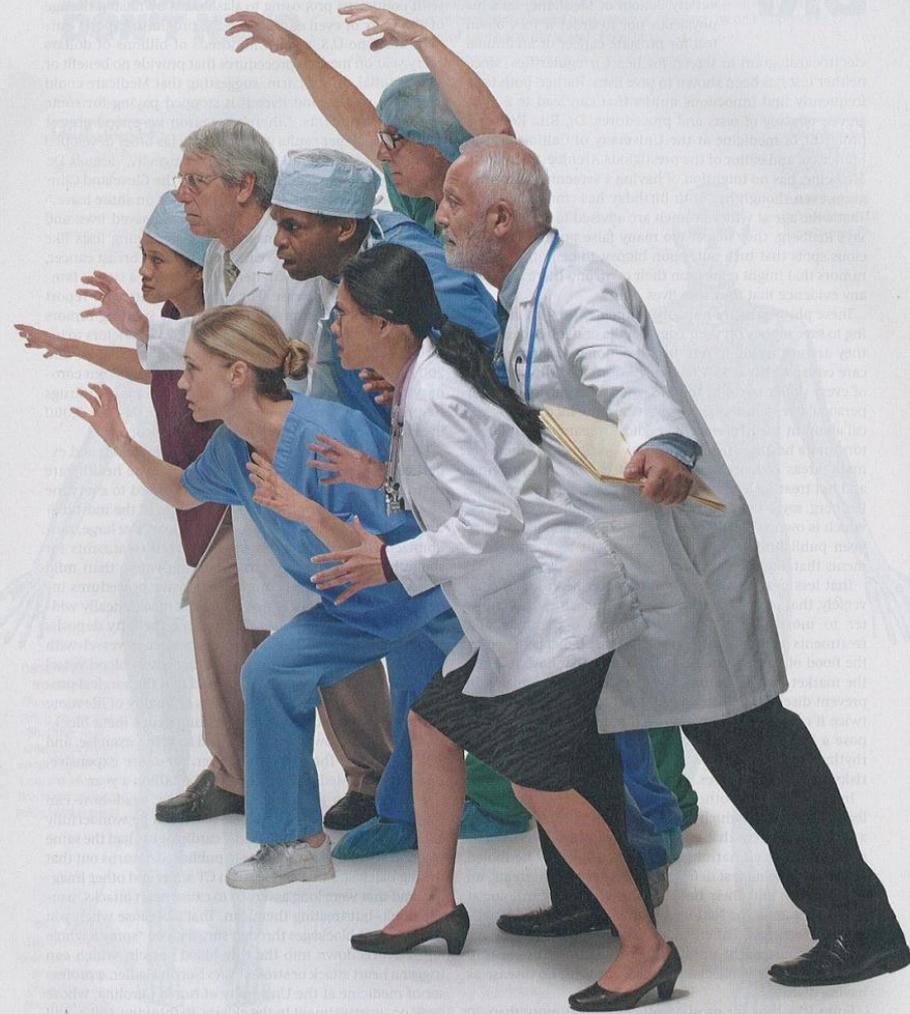


NO!



**THE
ONE WORD
THAT
CAN SAVE
YOUR
LIFE**

BY SHARON BEGLEY
PHOTOGRAPH BY HUGH KRETSCHMER



STENTS. KNEE SURGERY. EVEN THE OMNIPRESENT MRI. NEW RESEARCH SHOWS HOW SOME

COMMON TESTS AND PROCEDURES AREN'T JUST EXPENSIVE, BUT CAN DO MORE HARM THAN GOOD.





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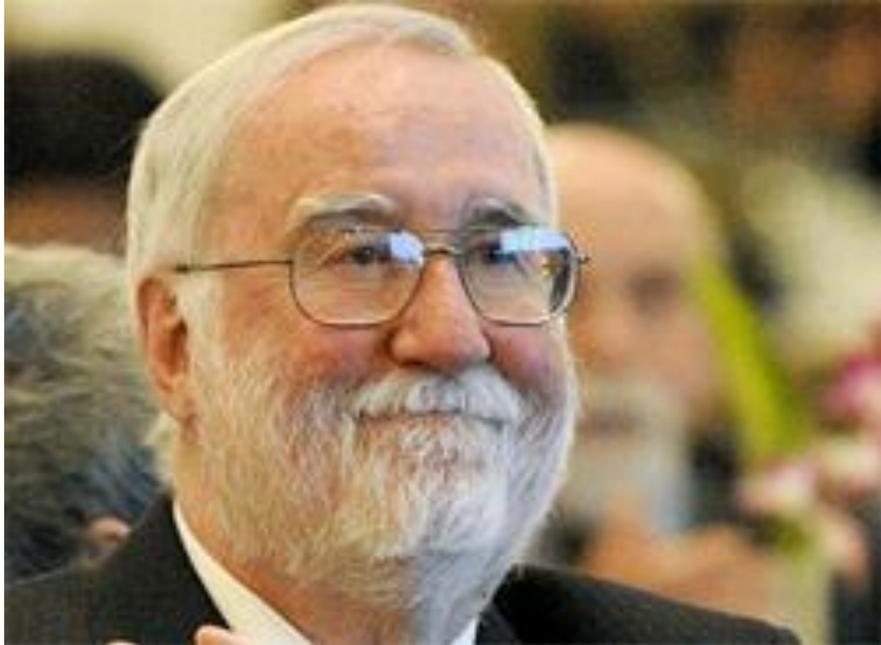
The intense current
interest in
complementary and
integrative health
reflects, in part, patient
dissatisfactions with
mainstream medicine.

Can we avoid drugs?

Can I foster the healing process
myself?

Patients at the Center

- Patients have long been ‘symbolically at the table’, but only in a check-the –box sort of way; (Ellen Sigal, quoted in NEJM 10/12)
- Information that patients value may go beyond the questions that trials typically try to answer;
- Patients remind researchers of quality of life issues: “I would never enroll in a trial like that.”



Evidence based medicine: what it is and what it isn't

It's about integrating individual clinical expertise and the best external evidence

David L Sackett, William M C Rosenberg, J A Muir Gray, R Brian Haynes, W Scott Richardson

medicine means integrating *individual clinical expertise* with the best available external clinical evidence from systematic research. ...”

mean... the more thoughtful
identification and compassionate use
of individual *patients' predicaments,*
rights and preferences."

patients' predicaments

patients' rights

patients' preferences

Evidence-based health care

predicaments

The challenge of truth
telling

The importance of
evidence

The challenge of
misinformation

■ Lung cancer (N=710) ■ Colorectal cancer (N=483)



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CME >

ORIGINAL ARTICLE

Patients' Expectations about Effects of Chemotherapy for Advanced Cancer

Jane C. Weeks, M.D., Paul J. Catalano, Sc.D., Angel Cronin, M.S., Matthew D. Finkelman, Ph.D., Jennifer W. Mack, M.D., M.P.H., Nancy L. Keating, M.D., M.P.H., and Deborah Schrag, M.D., M.P.H.

N Engl J Med 2012; 367:1616-1625 | [October 25, 2012](#) | DOI: 10.1056/NEJMoa1204410

Somehow
A.L.
Not an
Don't
No

Table 2. Odds Ratios for the Association between Various Factors and an Inaccurate Response to Questions about the Likelihood of Cure with Chemotherapy.*

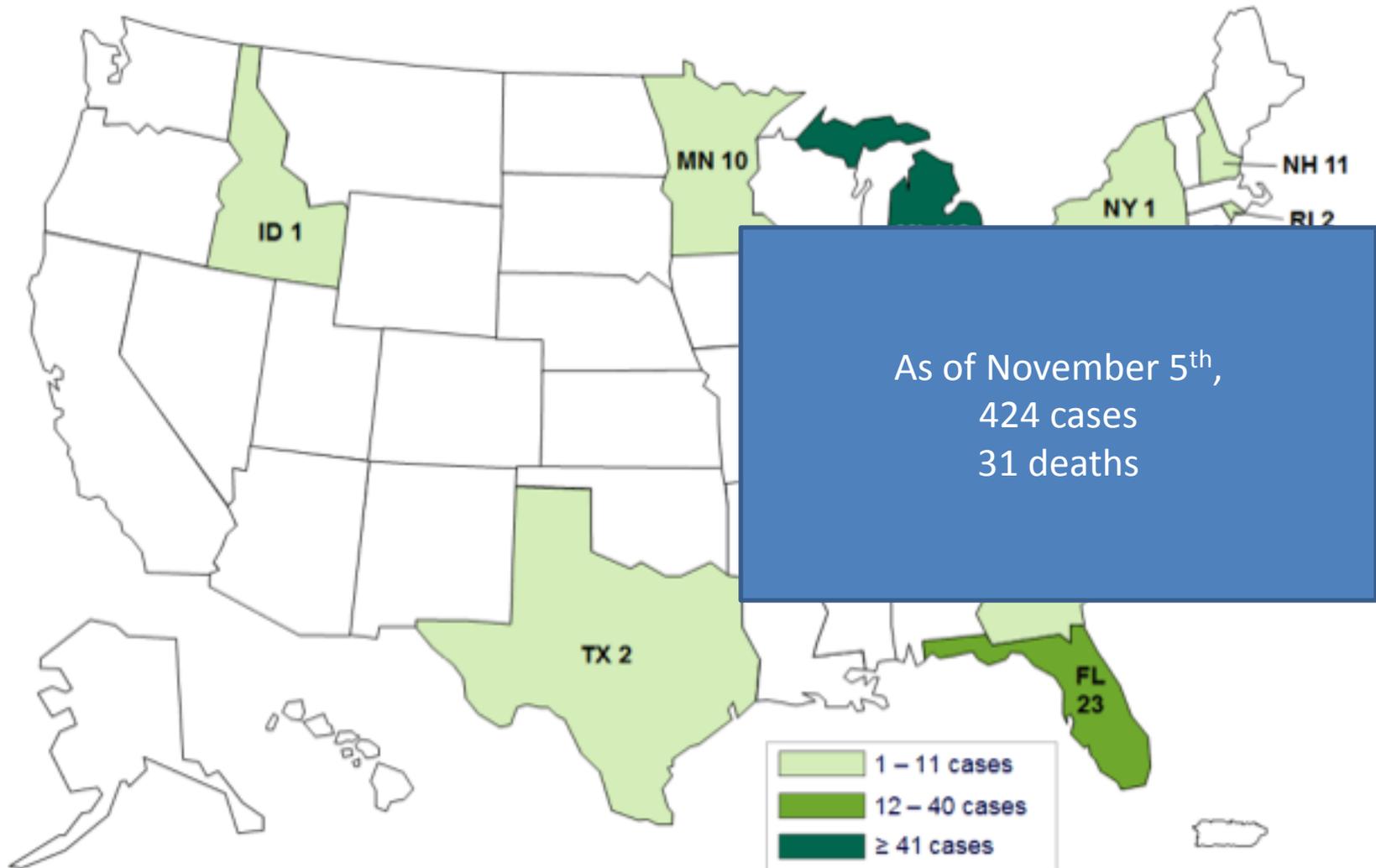
Variable	Odds Ratio (95% CI)	P Value
Cancer type		<0.001
Lung	Reference	
Colorectal	1.75 (1.29–2.37)	
Age		0.06
21–54 yr	Reference	
55–69 yr	1.10 (0.77–1.57)	
70–79 yr	1.68 (1.10–2.57)	
≥80 yr	1.47 (0.77–2.80)	
Race or ethnic group		<0.001
White	Reference	
Hispanic or Latino	2.82 (1.51–5.27)	
Black	2.93 (1.80–4.78)	
Asian or Pacific Islander	4.32 (2.19–8.49)	
Other	3.07 (1.50–6.27)	
Integrated health care network		0.02
No	Reference	
Yes	0.70 (0.52–0.94)	
Baseline interview type		0.06
Full	Reference	
Brief	2.32 (1.03–5.26)	
With surrogate for ill patient	0.80 (0.54–1.19)	
Physician-communication score		0.002
0–79	Reference	
80–99	1.37 (0.93–2.02)	
100	1.90 (1.33–2.72)	

* Odds ratios were calculated with the use of multivariable logistic regression. An odds ratio of more than 1 represents a greater likelihood of an inaccurate belief. Listed are variables with $P < 0.10$ in the multivariable model. Full results for all variables that were included in the multivariable model are provided in Table S2 in the Supplementary Appendix.

- Truth telling

Cases with Fungal Infections Linked to Steroid Injections

NOTICE: Next update will be Monday Nov. 5.



[\[View Larger Map\]](#)

Cases and Deaths with Fungal Infections Linked to Steroid Injections



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ORIGINAL ARTICLE

A Controlled Trial of Corticosteroid Injections into Facet Joints for Chronic Low Back Pain

Simon Carette, M.D., Sylvie Marcoux, M.D., Ph.D., René Truchon, M.D., Charlotte Grondin, M.D., Jacques Gagnon, M.D., Yves Allard, M.D., and Marie Latulippe, R.N.

N Engl J Med 1991; 325:1002-1007 | [October 3, 1991](#) | DOI: 10.1056/NEJM199110033251405



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Injection therapy for subacute and chronic low-back pain

Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P

Published Online: February 16, 2011

Injection therapy is one of many treatments available for patients with subacute (longer than six weeks) and chronic (longer than 12 weeks) low-back pain. Where the injection is given, what drug is used and why the injection is given can all vary.

The injection can be given into different parts of the spine (the space between the vertebrae, around the nerve roots, or into the disc), ligaments, muscles or trigger points (spots in the muscles that when pressed firmly will produce pain). Drugs that reduce swelling (corticosteroids, non-steroidal anti-inflammatory (NSAIDs)) and pain (morphine, anaesthetics) are used. Injection therapy can be used for individuals with low-back pain with or without pain and other symptoms in the leg.

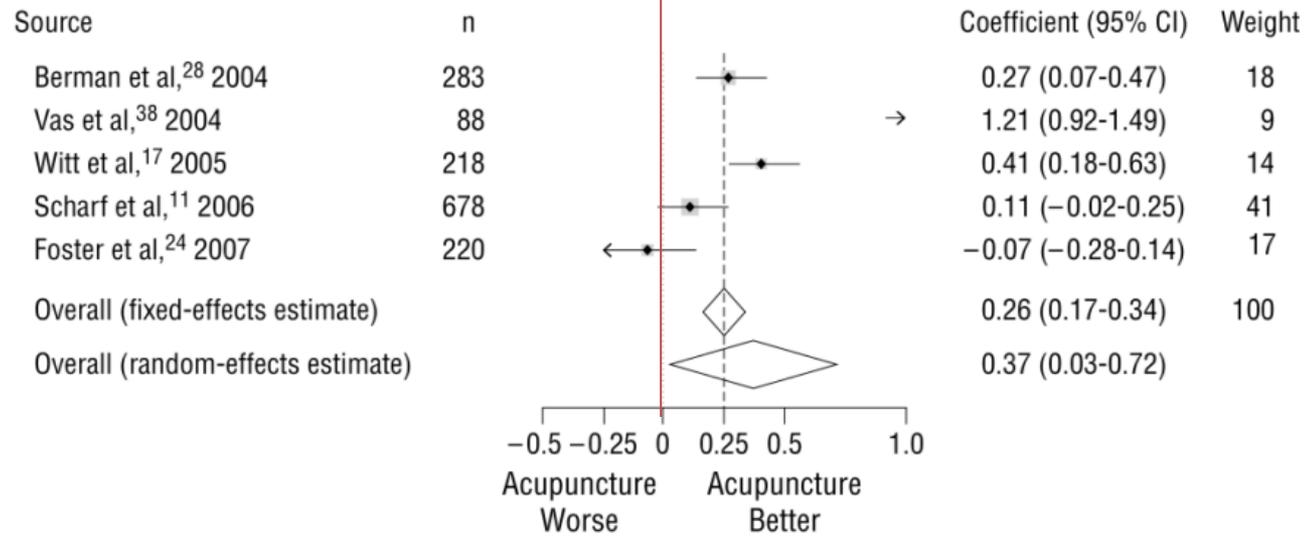
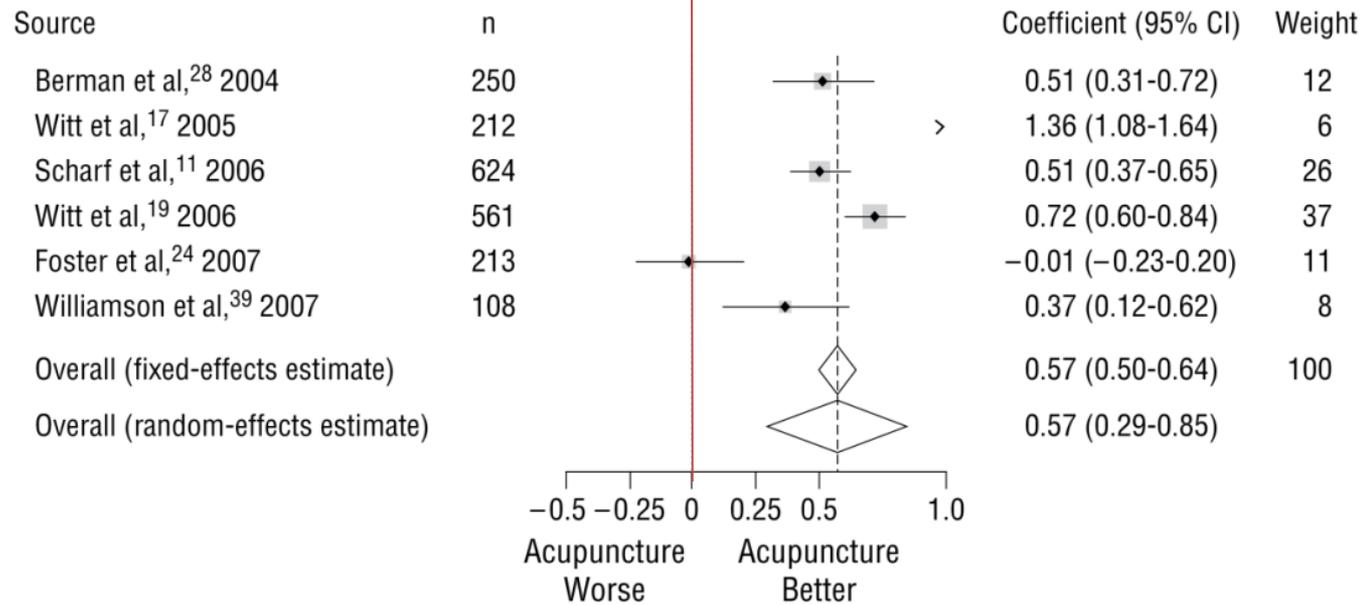
Find the research

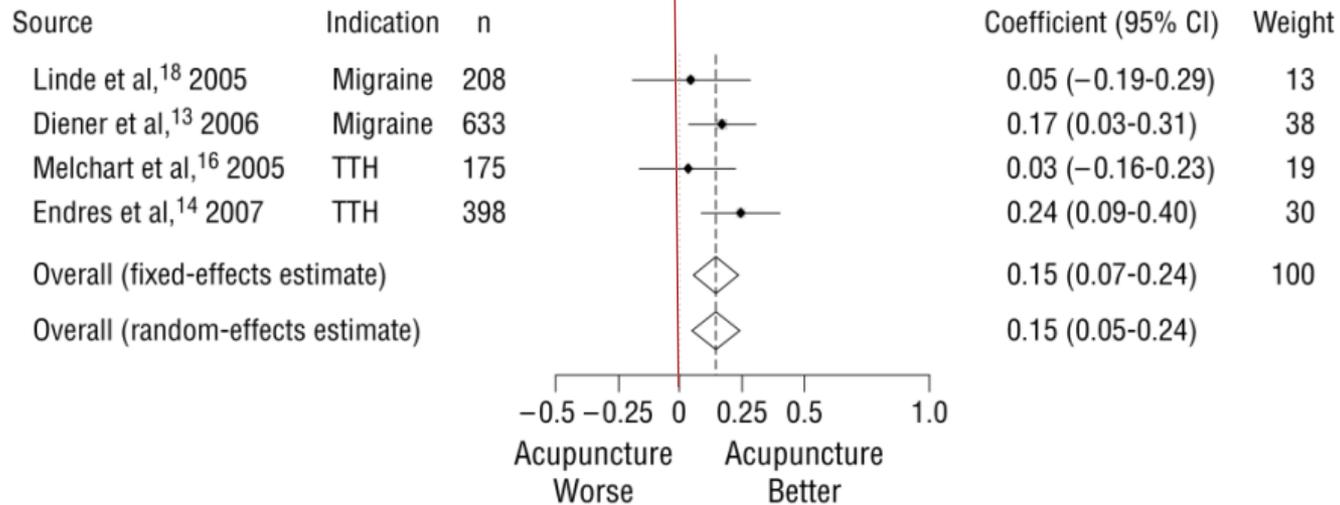
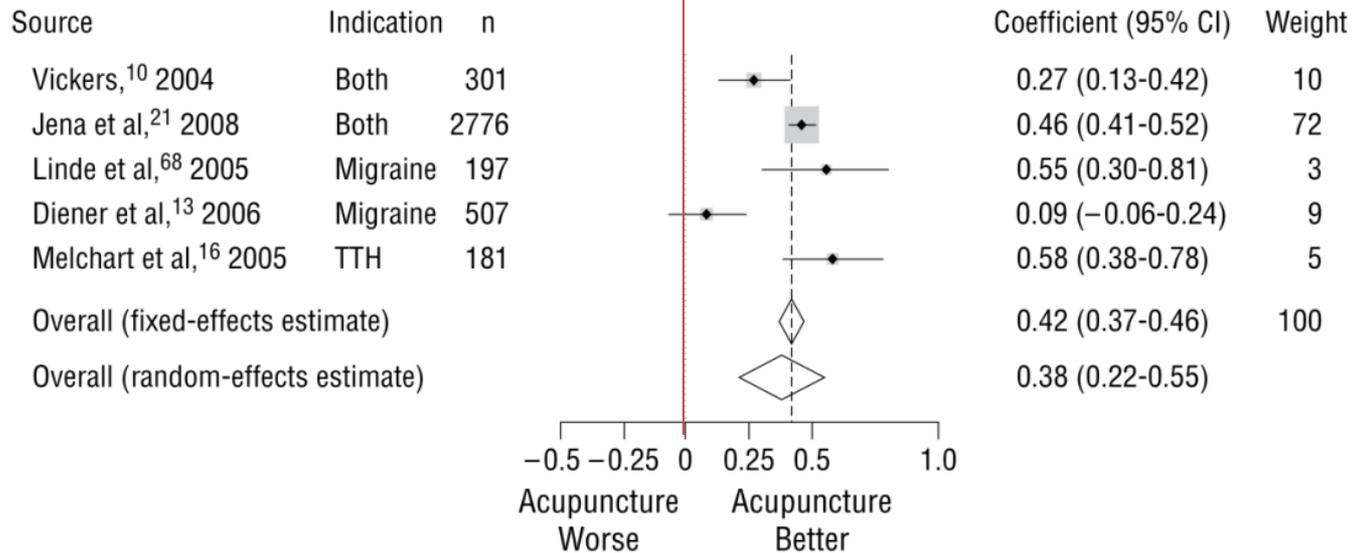
Get full text in *The Cochrane Library* for this Review titled:

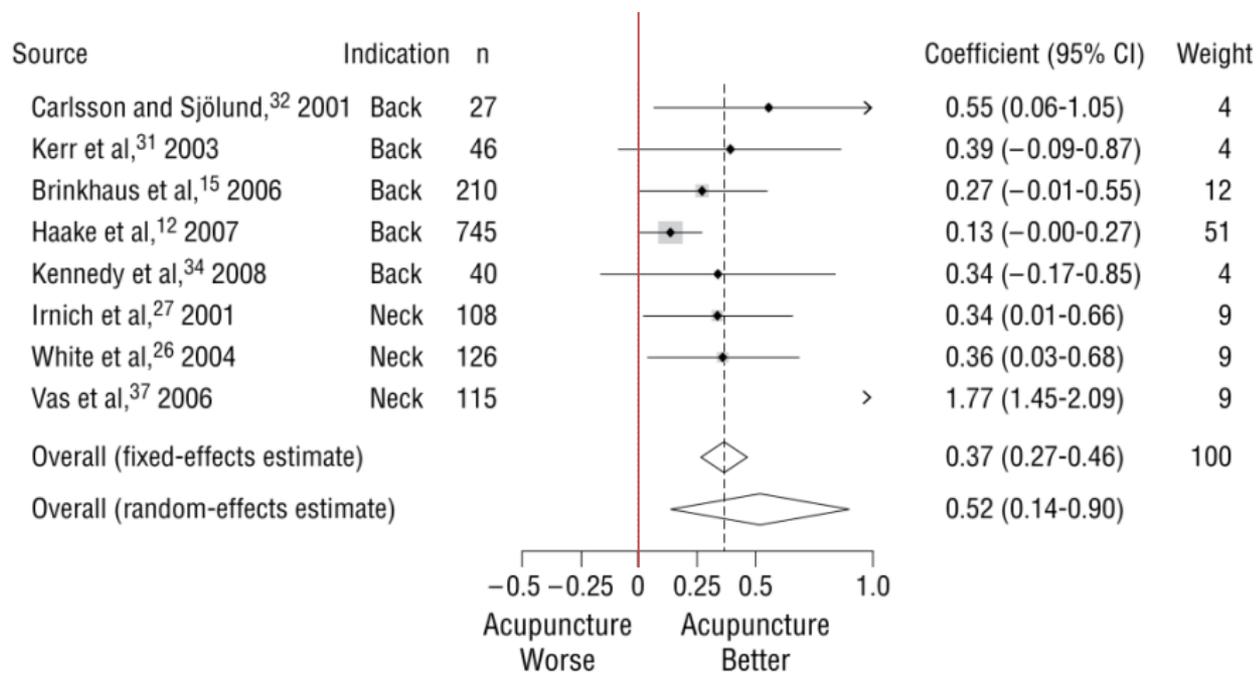
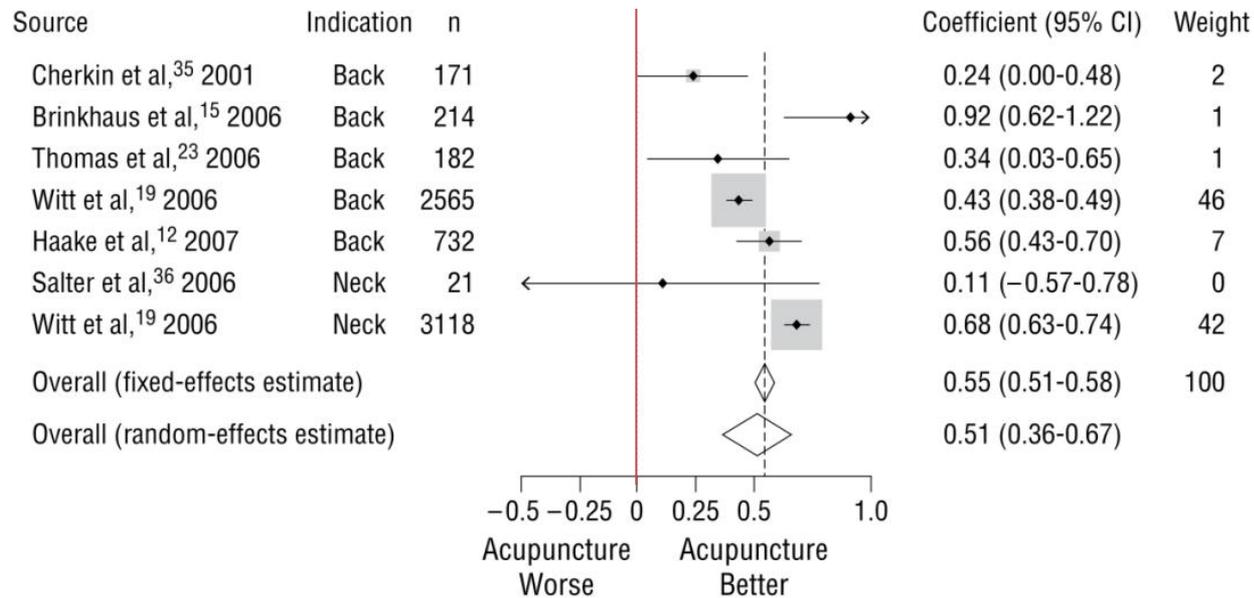
[Injection therapy for subacute and chronic low-back pain](#)

Primary Review Group: [Back Group](#)











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FTC Consumer Alert

THIS JUST IN: Fake News Sites Promote Bogus Weight Loss Benefits of Acai Berry Supplements

When you want the straight scoop on what's going on in your community or around the world, you probably count on the news for accurate and truthful reporting. More and more, scam artists are exploiting your trust in well-known news organizations by setting up fake news sites to peddle their wares. The fake sites, which usually display logos of legitimate news organizations, promote everything from bogus weight loss products to work-at-home opportunities, anti-aging products and debt reduction plans.

Getting to the What, When, Where, Why and How

- [Acai](#) (PubMed® Citations)

Other Resources

- [Acai](#) (MedlinePlus)
- [FTC Scam Watch Video: Free Trial Offers](#) (FTC)



OW

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Featured Topic of the Month

Yoga

Includes a Message from the Director, Time to Talk Tips, NCCAM Clinical Digest, and more.

Learn more ▶

1 2 3 4



Research Results

Highlights of recently published studies funded by NCCAM.

-  **Effects of Milk Thistle Extract on Chronic Hepatitis C** (July 18, 2012)
-  **Meditation or Exercise May Help Acute Respiratory Infections, Study Finds** (July 9, 2012)

See more research results ▶

 **Resources for Health Care Providers** ▶

- ### News
- Reumofan Products Pose Risk to Consumers: Updated Alert (FDA; 08/21/12)
 - Message From the Director: The Science of Yoga for Health and Well-Being (08/14/12)
 - Renowned Researcher to Lead New Multidisciplinary Pain Program at NIH (07/12/12)
 - Job Opening: Deputy Director, NCCAM [Deadline: 09/17/12]
 - In the News: Silymarin for Hepatitis C
- See all news items** ▶

READ THE NEW NCCAM Research Blog

What does NCCAM do? ▶
We conduct and support research and provide information about complementary health products and practices.

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NCCAM's Time to Talk Campaign

TIME TO TALK



Time to Talk is an educational campaign to encourage patients and their health care providers to openly discuss the use of complementary health practices. When patients **tell** their providers, they can more effectively manage their health. When providers **ask** their patients, they can ensure that they are fully informed and can help patients make wise health care decisions. Simply put—it's time to talk!

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Resources for Health Care Providers

The evidence-based resources on this page, such as research results and clinical practice guidelines, will help prepare you to discuss CAM approaches with your patients.

[Take a video tour of this resource](#) ▶

research spotlights

Long-Term Effects of Isoflavone-Rich Soy Protein on Cognition in Postmenopausal Women

[Read more](#) ▶

1 2 3 4 5



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Evidence, from acupuncture to zinc.

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[Printable fact sheets](#) and links to more resources.

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Clinical Practice Guidelines

Full-text guidelines for oncologists, rheumatologists, general medicine practitioners, and more.

NCCAM Clinical Digest Newsletter

Monthly e-newsletter that summarizes the state of the science on complementary health practices and a health condition.

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TIME TO TALK

DISCUSS use of complementary health practices

nccam.nih.gov/timetotalk

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Childhood Vaccinations

Matern Child Health J (2010) 14:922–930
DOI 10.1007/s10995-009-0519-5

Pediatric Vaccination and Vaccine-Preventable Disease Acquisition: Associations with Care by Complementary and Alternative Medicine Providers

Lois Downey · Patrick T. Tyree · Colleen E. Huebner ·
William E. Lafferty

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NCCAM clinical digest

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Childhood Vaccinations/Immunizations



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Parents want to feel confident that they are making the best health care decisions for their children. This confidence can be undermined when there is conflicting information in the media and on the Internet. Nowhere is this more prevalent than when it comes to the topic of the safety of childhood vaccines.

The value and safety of vaccinating children against dangerous illnesses cannot be overstated.

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