



Cost Verses Benefit of Nutrients from Survey Studies

Based on The Hierarchy of Evidence “Association Among Tiers”

Michael A. Morton, Ph.D.
Executive Director, Nourish America
P.O. Box 567, Ojai, CA 93023
michael@nourishameria.org



improving lives, everyday

Thank you!

- National Health Research Institute - Board and Members
- NOW Foods
- And, YOU!

Overview

1. Relevant Studies: The Lewin Group, NICM, Fish Oils, Others
2. Nourish America: Mission / Observational Surveys
3. Hierarchy of Evidence / “Association Among Tiers”
4. Questions / Close

Methods of Evaluating Food & Nutrition Policies: How do we assess costs in relation to effect and benefit, and against alternative programs Kevin D. Frick, PhD Department of Health Policy and Management, John Hopkins Bloomberg School of Public Health, September 16, 2005.

A Little Perspective

How the “meta” is defined, i.e. what criteria are used to determine credibility for inclusion in the analysis, determines the outcomes achieved and the conclusions drawn.

“Develop estimates of potential health care cost savings that could result from only those supplements for which the **highest standard of evidence** exist at the time.” *The Lewin Group.*

One researcher's highest standard of evidence is not necessarily another researcher's highest standard of evidence.

Consider 2006 ODS/NIH conference inclusion standards on MVM use *as compared to* The Lewin Group's inclusion standard.

The Lewin Group Meta-Analysis'

Five Studies between October 2002 and June 2007, examined results of existing scientific research. Commissioned by Wyeth (1) and DSEA (4) (DSIB)

Studies focused on 65+ year old population within health insurance context, women of childbearing age, and diabetics.

All studies were conservative estimates. Used Congressional Budget Office accounting methods.

DaVanzo JE, Dobson A, et al. (2004) *A Study of the Health and Cost Effects of Five Dietary Supplements*. Falls Church, VA: The Lewin Group

Nutrient Intervention Criteria

1. The supplement had to produce a measurable physiological effect.
2. This physiological effect had to create a change in health status.
3. Only looked at health problems where a change in health status is associated with a decrease in healthcare expenditures.

DaVanzo JE, Dobson A, et al. (2004) *A Study of the Health and Cost Effects of Five Dietary Supplements*. Falls Church, VA: The Lewin Group.

I. "Study of the Cost Effects of Daily Multivitamins for Older Adults" October 2, 2003

- ✓ Economic impact of the use of daily multivitamins by 65+ adults within health insurance context (e.g., Medicare, or some other payer..., Over five year period from 2004-2008.
- ✓ Systemic literature review of most rigorous clinical studies available. Analyzed Medicare claim files with CBO cost accounting methods.
- ✓ Estimates are conservative: Did not account for ambulatory care savings, assumed only 1/3 of seniors would benefit, used average savings effect for each of five years.

DaVanzo JE, Dobson A, et al. (2003) *A Study of the Cost Effects of Daily Multivitamins for Older Adults*.
Falls Church, VA: The Lewin Group.

Key Findings

\$1.6 billion net savings from multivitamins in 65 & older Medicare Population from reduction of CAD, improved immune functioning, and reduction in infection.

Given that "...a significant number of older adults fail to get the amounts and types of food necessary to meet essential energy and nutrient needs."1, Then,

"In summary, given the available evidence, we conclude that daily multivitamins can be beneficial for older adults. Because suboptimal nutrient intake has been linked to chronic disease, the risk of NOT taking a multivitamin outweighs the minimal risk of taking one."2

1. McCormack P. (1997). *Undernutrition in elderly population living at home in the community: a review of the literature*. J. Adv. Nurs. 26:856-863.

2. DaVanzo JE, Dobson A, et al. (2003) *A Study of the Cost Effects of Daily Multivitamins for Older Adults*. Falls Church, VA: The Lewin Group.

II. "Improving Public Health, Reducing Health Care Costs: An Evidence-Based Study of Five Dietary Supplements" 2004

- ✓ Focus on high-risk disease conditions: coronary artery disease (CAD), colorectal cancer, diabetes, osteoporosis prostate cancer, and immune function.
- ✓ FDA approved health claim supplements reviewed: Calcium/Vit D, Folic Acid, Omega-3 Fatty Acids, Glucosamine, & Saw Palmetto.
- ✓ Cost estimates for Calcium/Vit D, and Folic acid.
- ✓ Estimates for five years (2005-2009).

DaVanzo JE, Dobson A, et al. (2004) *A Study of the Health and Cost Effects of Five Dietary Supplements*. Falls Church, VA: The Lewin Group.

Key Findings

\$13.9 billion net savings with Calcium/Vitamin D in hospital, nursing facility, and physician expenditures.

Approximately 734,000 hip fractures could be avoided over five years in 65+ population from daily intake of 1200 mg calcium.

\$1.3 billion net savings with Folic Acid: Over five years, \$1.3 billion savings in lifetime cost from prevention of NTD/Spina Bifida in 600 babies.

Given the promising state of the research, recommended further studies for Omega 3 Fatty Acids.

DaVanzo JE, Dobson A, et al. (2004) *A Study of the Health and Cost Effects of Five Dietary Supplements*. Falls Church, VA: The Lewin Group.

III. "An Evidence-Based Study of the Role of Dietary Supplements in Helping Seniors Maintain their Independence" ***January 20, 2006***

Purpose: "... (1) to critically review of research literature for two dietary supplements for which an association has been shown between intake of the supplement and reduced risk of disease that can and does lead to a loss of independence, and (2) to develop estimates of potential health care savings that could result from daily use of the supplement."

- ✓ Omega-3 fatty acids for Coronary Heart Disease (CHD)
- ✓ Lutein/Zeaxanthin for Age-Related Macular Degeneration (AMD)
- ✓ Vitamin D as it relates to Osteoporosis.

DaVanzo JE, Dobson A, et al. (2006). *An Evidence-Based Study of the Role of Dietary Supplements in Helping Seniors Maintain their Independence*. Falls Church, VA: The Lewin Group.

Key Findings

\$3.1 billion net savings from Omega-3 fatty acids in hospital and physician charges from 2006-2010. Approximately 384,303 hospitalizations from CHD could be avoided.

\$2.5 billion cost savings with Lutein with Zeaxanthin from AMD risk reduction.

Vitamin D: Not enough studies to make any meaningful determinations.

DaVanzo JE, Dobson A, et al. (2006). *An Evidence-Based Study of the Role of Dietary Supplements in Helping Seniors Maintain their Independence*. Falls Church, VA: The Lewin Group.

IV. "A Study of Dietary Supplement Use among People with Diabetes" June 19, 2006

Purpose

- 1.** To determine if dietary supplements are associated with better health among the general population.
- 2.** To create a profile of people with diabetes who use dietary supplements.
- 3.** To determine whether diabetics who use dietary supplements manage their condition differently than diabetics who do not use supplements.

The Lewin Group. (2006). *A Study of Dietary Supplement Use among People with Diabetes - Draft Report.*

Key Findings

- “1) Use of dietary supplements is significantly associated with reporting oneself to be in better health than a year ago...
- 2) Diabetics report significantly worse health than their nondiabetic counterparts...
- 3) About 34% of diabetics take dietary supplements...
- 4) Diabetic supplement users are more likely to engage in protective health behaviors...
- 5) Diabetic supplement users report being in better health than diabetics who do not use supplements in univariate analyses.”

The Lewin Group. (2006). *A Study of Dietary Supplement Use among People with Diabetes - Draft Report.*

V. "Effect of Selected Dietary Supplements on Health Care Cost Reduction - Study Update/Final Report" 2008

Updated earlier analysis of the five year (2008-2012) health benefits and cost effects of daily use of:

- ✓ Calcium with Vitamin D and Hip Fractures
- ✓ Folic Acid and Neural Tube Defects
- ✓ Omega-3 Fatty Acids and CHD
- ✓ Lutein with Zeaxanthin and AMD

DaVanzo JE, Dobson A, et al. (2008). *Effect of Dietary Supplements on Health Care Cost Reduction Key Study Findings.*

Key Findings

\$16.1 billion savings with Calcium with vitamin D for hip fractures.

776,000 avoided Medicare hospitalizations for hip fractures, as well as avoidance of stays in skilled nursing facilities for some proportion of patients associated with avoidable hospitalization.

\$1.4 billion saved with Folic Acid: If just 11.3 million of the 44 million American women who are of childbearing age and not taking folic acid, began taking 400mcg. of folic acid on a daily basis, neural tube defects could be prevented in 600 babies, saving as much as \$344,700,000 in the first year.

DaVanzo JE, Dobson A, et al. (2008). *Effect of Dietary Supplements on Health Care Cost Reduction Key Study Finding*

Key Findings (Continued)

\$3.2 billion savings from Omega-3 Fatty Acids from a reduction in the occurrence of CHD in population over age 65 through daily use.

Approximately 374,301 hospitalizations and associated physician fees due to CHD could be avoided.

\$3.6 billion in savings from Lutein with Zeaxanthin by helping people with age related macular degeneration avoid dependency.

Across the five year period, approximately 190,927 individuals could avoid the transition to dependence either in the community or a nursing facility that would accompany a loss of central vision resulting from advanced AMD.

DaVanzo JE, Dobson A, et al. (2008). *Effect of Dietary Supplements on Health Care Cost Reduction Key Study Finding*

*Summary
of
Lewin Group Meta-Analysis Estimate Five Year Net Costs*

- ✓ \$1.6 billion net savings from multivitamins in Medicare population from reduction of CAD, improved immune functioning, and reduction in infection.
- ✓ \$16.1 billion saving with 1200 mg/day Calcium with Vitamin D for hip fractures in Medicare population.
- ✓ \$3.6 billion savings from 6-10 mg/day Lutein with Zeaxanthin for AMD.
- ✓ \$1.4 billion saved with 400 mcg/day Folic Acid in prevented lifetime cost of NTD/Spina Bifida in 600 babies.
- ✓ \$3.2 billion savings from 1800 mg/day Omega-3 Fatty Acids from reduction in the occurrence of CHD in Medicare population.

"Cost effectiveness of complementary medicines"
August 2010

Commissioned by:
The National Institute of Complementary Medicine (NICM AUS)

Key Findings

Acupuncture for chronic back pain is cost effective as a complement to standard care, not generally cost effective as a replacement to standard care.

St. John's Wort is cost effective for mild to moderate depression: compared to standard anti-depressants due to lower dosage unit cost.

Omega 3 fish oils are not cost effective for reduction of non-steroidal anti-inflammatory drug use in rheumatoid arthritis.

Phytodolor an herbal medicine has a cost savings for pain and inflammation of osteoarthritis compared to Diclofenac /non-steroidal anti-inflammatory drug.

"Cost effectiveness of complementary medicines"

August 2010

Key Findings: Omega 3 fish oils and CHD

\$39.6m/year AU (\$38.8m/year US). Cost (read: "savings") of administering fish oil intervention to those already with MI.

19,424 DALY/ (disability-adjusted life years) averted per year in CHD population of 309,726. Cost saving of one DALY was \approx AU\$2,041 (US\$2,010).

➤ Omega-3 fish oils are highly cost effective for secondary prevention of heart disease as adjunctive treatment in people with history of CHD by achieving reduced death and morbidity as compared to MI patients without adequate amounts of oily fish to meet the recommended intake of (EPA) and (DHA).

➤ **The use of fish oil supplements was shown here to be a cost effective intervention to prevent future cardiovascular mortality in Australia.**

Access Economics Pty Limited. (2010). *Cost effectiveness of complementary medicines*. ABN 82 113 621 361.

Omega 3-Fatty Acids anti-inflammatory and anti-diabetic effect mechanism identified

GPR120 (G protein coupled receptor) is a functional receptor/ sensor for Omega 3 fatty acids on macrophages and fat cells.

Activation of GPR120 inhibits multiple inflammation cascades in macrophages and reverses insulin resistance in obese mice.

This mediates potent insulin sensitizing and anti-diabetic effects in vivo by repressing macrophage-induced tissue inflammation.

Oh, D, et al. *GPR120 is an Omega-3 Fatty Acid Receptor Mediating Potent Anti-inflammatory and Insulin-Sensitizing Effects.* Cell. 2010; 142(5): 687-698.

U.S Army Approves Omega 3 Study

Lt. Col. Daniel Johnston brigade surgeon, serving in Iraq received approval to study the effects of omega-3 fish oil capsules on deployed soldiers' mental health.

The study will be conducted to determine whether the nutrients may be used to enhance deployed soldiers' resilience to mood related disorders.

The effects of the capsules will be measured by a set of psychological tests, and the data will be compared to the results of a placebo drug.

Johnston's hypothesis is that soldiers taking the omega-3 supplements will exhibit higher cognitive performance, better mood state, and fewer combat symptoms.

The drug company GlaxoSmithKline donated 100,000 capsules to the study.

Around 250 service members from three U.S. bases in Iraq will participate in the study on an all-volunteer basis.

www.army.mil/-news/.../45778-omega-3-study-approved-in-iraq/

Other Relevant Studies

- ✓ R K Chandra, M.D. in September 2001 issue of *Nutrition*, shows that a supplement with moderate amounts of 18 vitamins, minerals, trace elements improves short-term memory, overall cognitive abilities, greatly strengthens immune systems of seniors.
- ✓ H Wang, M.D study in the May 2001 issue of *Neurology* links poor nutrition to Alzheimer's disease. Seniors 75 and older had low blood levels of folate and vitamin B12 have an increased risk of developing Alzheimer's disease.
- ✓ In August 2001 issue of *Nutrition* TA Marshall, M.D. found that nutritional deficiencies greatly increase with age, that supplement use would eliminate these deficiencies in the elderly. Those 78+ years old, 80% consumed inadequate amounts of four or more nutrients.

http://www.naturalproductsinfo.org/index.php?src=news&submenu=News&srctype=detail&category=DSIB%20Releases&efno=109&view=DSIB_Releases_Detail

Mission Statement

Nourish America™ improves the health status of children, families, and seniors at risk for malnutrition.

We do this.

by providing vitamin supplements, nourishing foods (including organics and naturals) as well as nutrition education and research.



improving lives, everyday

Strengthening Our Next Generation

Healthy Moms & Babies:

Providing low income pregnant mothers-to-be the prenatal multi-vitamin support they need to assure a healthy pregnancy and healthy babies at birth.

Children First:

Providing nourishing foods and supplements to help low income children thrive both at school and in life.

Teen Support:

Supplying teens with nutrients to support healthy growth, emotional balance and success.



Other Nourish America programs include:



Senior Support:

Assuring that our senior citizens have the basic nutrients they need to keep up their energy, their health and their independent living.



Disaster Response:

Helping those in need in times of crisis with nourishment and support.



Operation Vital Nutrients:

Providing much needed multivitamins and other nutrients to our citizen soldiers- the National Guard.

Nourish America owes its success to an innovative model of collaboration driven by the belief that every American, regardless of socio-economic status, deserves to receive the basic nourishment that is essential for health and well-being.

In this way we significantly reduce the escalating cost to the American people to care for those in need while also improving the health and well-being of all our citizens.



Nourish America Observational Survey for Seniors

Each year Nourish America conducts an observational survey with its program sites in order to gauge the impact of its micro-nutrient distribution programs.

Both staff and participating seniors reported observed changes since the seniors began taking the supplements at least six months prior.

✓ **NOT** a study of direct intervention with regard to causal relationship; *only an association.*

✓ Does **not** protect against systemic bias, non-systemic bias, inferential error.

✓ Only NA program sites serving recurring low income senior populations.

✓ Supplements: Centrum/Centrum Silver and Centrum Caltrate w/Vitamin D.

Nourish America Observational Survey for Seniors

Number of Participating Seniors: 204 of \approx 1,400 Served.

Women: 72%

Men: 31%

Participation Rate:

82% Always / everyday

10% Almost always- 9 out of 10 times

6% Most the time - 7 out of 10 times

0% About half the time

1% Very seldom - 2 out of 10 times

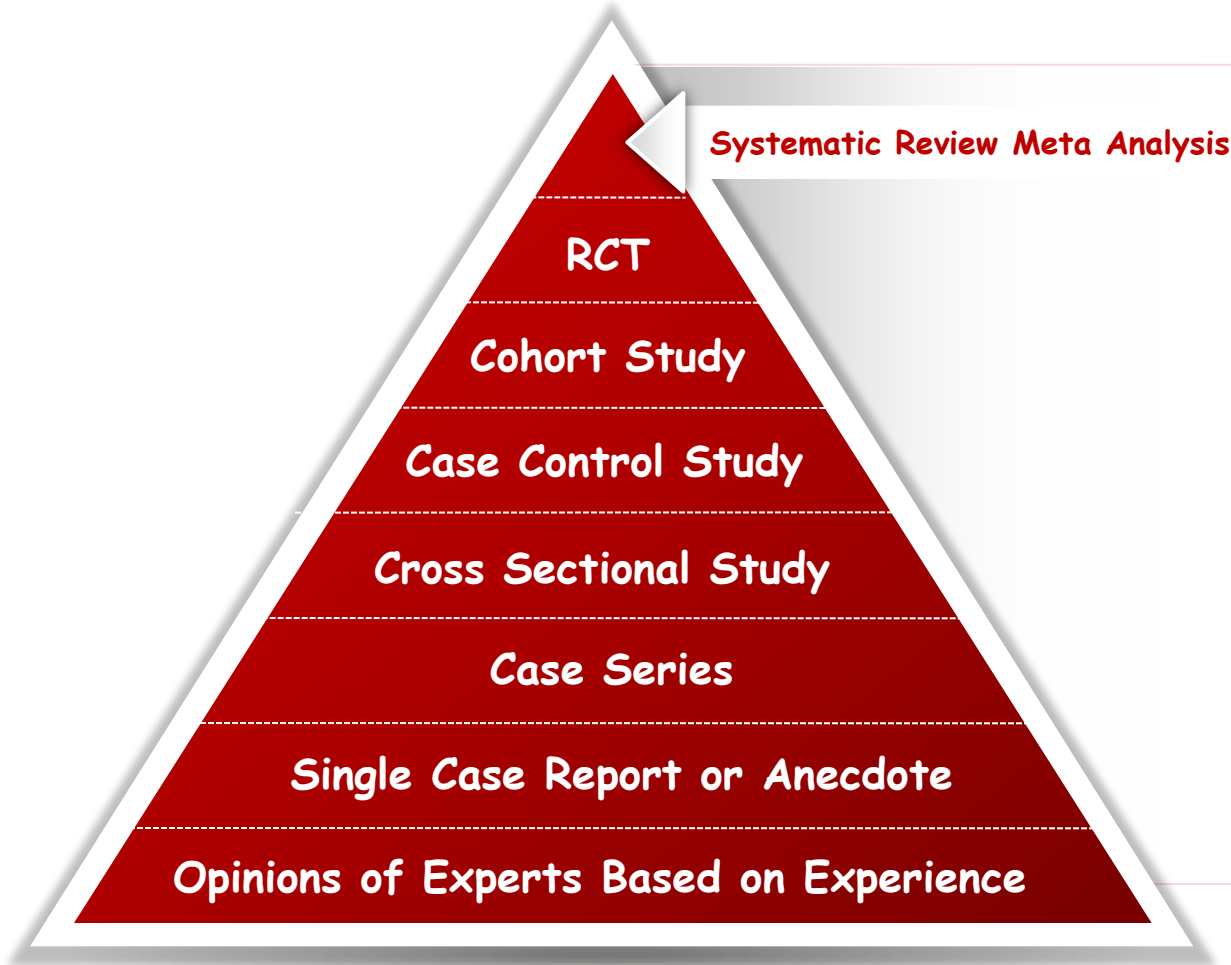
Sites:

YMCA of Riverside, CA

City of Riverside Parks & Recreation Department

Riverside Medical Clinic (4 sites)

Hierarchy of Evidence: "Associations Among Tiers"



DaVanzo JE, Dobson A, et al. (2003) *A Study of the Cost Effects of Daily Multivitamins for Older Adults*. Falls Church, VA: The Lewin Group, pg. v

Senior "Snowball Effect" Cycle

Stuart Reeves, Ph.D.

Director of Research and Development Embria Health Sciences

Loss of appetite > Inadequate nutrition > Decreased energy >

Reduction in social activities > Decreased independence > Limited social interaction >

Increased potential for depression and stress > Weakened immune system >

Continued illness > Loss of appetite >

Hierarchy of Evidence Associations

Multi-Vitamin Mineral for Low Income Seniors

Top Tier Research Outcomes

Reduction in CAD
Improved Immune Function
Reduced Infection
Improved Short Term Memory
Improved Cognitive Abilities
↓ Hospitalizations
↓ SNF Stays
↓ Home Health Costs
↓ Colorectal Cancer*

Lower Tier Surveys Cofactors

Seniors/Staff
↑ Energy 63%/61%
↑ Physically Active 55%/50%
↑ Flexible 47%
↓ Body Pain 39%
Eating Better 52%/32%
Sleeping Better 46%
Not ill as often 45%/32%
Not ill as long/severe 40%/21%
↑ Concentration 42%/24%
Better Mentally 56%/37%
Better Emotionally 55%/39%
↓ Depressed 40%/34%
↓ Anger/Aggression 33%/24%
Better care of self 66%

Hierarchy of Evidence Associations

Calcium/Vitamin D for Low Income Seniors

Top Tier Research Outcomes

Significant ↓ hip fractures
Large ↓ nonvertebral fractures
↓ Hospital Costs
↓ SNF Stays/Costs
↓ M.D Costs

Lower Tier Surveys Cofactors

Seniors/Staff

↑ Energy 63%/61%
↑ Physically Active 55%/50%
↑ Flexible 47%
↓ Body Pain 39%
Eating Better 52%/32%
Better care of self 66%
Not ill as often 45%/32%
Not ill as long/severe 40%/21%
Sleeping Better 46%

How Has the Nourish America Program Helped You?

"I do have more pep and energy. I feel much better, and I can take better care of myself because of the extra energy."

-Dorothy Bevers, 79 years old

"I am able to cut back on a combination of various medicines on doctor's orders."

-C.W. Skilling, 76 years old

"I'm more active and don't get tired as much as I used to. I walk more and work more in my garden."

-Aurora Romo, 79 years old

How Has the Nourish America Program Helped You?

"My biggest surprise was more flexibility - small but being disabled and chronically ill, it's big for me. I just plain old feel better."

-Anon, 80 years old

"The seniors now seem to take an active role in their overall well-being. I see the seniors reading labels and asking questions. They have been very excited about sharing the benefit of this vitamin program with their friends at the senior center and their families."

-Samantha Patterson, Riverside Parks Coordinator

How Has the Nourish America Program Helped You?

"They recover faster from the flu season."

-Anon, YMCA Riverside

"Seniors look forward to this program. They are more active in the walking program and other activities we offer them."

-Frank Garcia, Recreation Aide, Riverside Prks/Rec

"The vitamin program keeps me active and alert. I can be active and moving around. It is a simple thing, ***but I have to keep moving.***"

Anon, 80 years old



It is less costly, both economically and socially, to PREVENT the negative consequences of malnutrition, than it is to deal with the painfully expensive aftermath.



For every dollar spent on prevention, our nation saves two dollars.