

# Nutritional Interventions for Chronic Disease Prevention

## Economic Analysis of Nutrition Interventions: Methods, Research and Policy

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# Office of Dietary Supplement Mission Statement

“The mission of ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.”

# ODS Strategic Plan Goals for 2010–2014

- Provide intellectual leadership by fostering research to analyze and evaluate the role of dietary supplements in promoting health and reducing the risk of disease.
- Expand the general scientific knowledge base on dietary supplements by funding new research and training.
- Support the development of research tools for the study of dietary supplements.
- Make the most up-to-date scientific knowledge about dietary supplements publicly available.

# Dietary Supplements

- ~1/2 of Americans take a dietary supplement
- ~1/3<sup>rd</sup> of Americans buy ~\$25 billion of multivitamins/minerals (MVM) per year
- ~65% Americans use fortified food or beverage ~\$36 billion per year

# Evidence-Based Review Program

- Mandated to review scientific evidence on the efficacy and safety of dietary supplements & identify research needs
- Partnership with AHRQ EPC Program: 17 reviews since 2003
  - B Vitamins and Berries; Ephedra; Multivitamin/Mineral Suppl; Omega 3-FA; Soy; Vitamin D

# MVM Efficacy in Chronic Disease Prevention in Adults

- Five RCTs in the US, UK, China, and France: 3-7 vitamins on cancer, CVD, cataract, AMD
- Substantial limitations
  - Cannot distinguish effects of individual components
  - Likely to be contaminated by MVM use in placebo group
  - Weaker biological basis than single-vitamin or mineral studies
  - Require very large sample sizes
  - Outdated because of the changing composition of commonly used MVMs

# MVM Efficacy in Chronic Disease Prevention in Adults

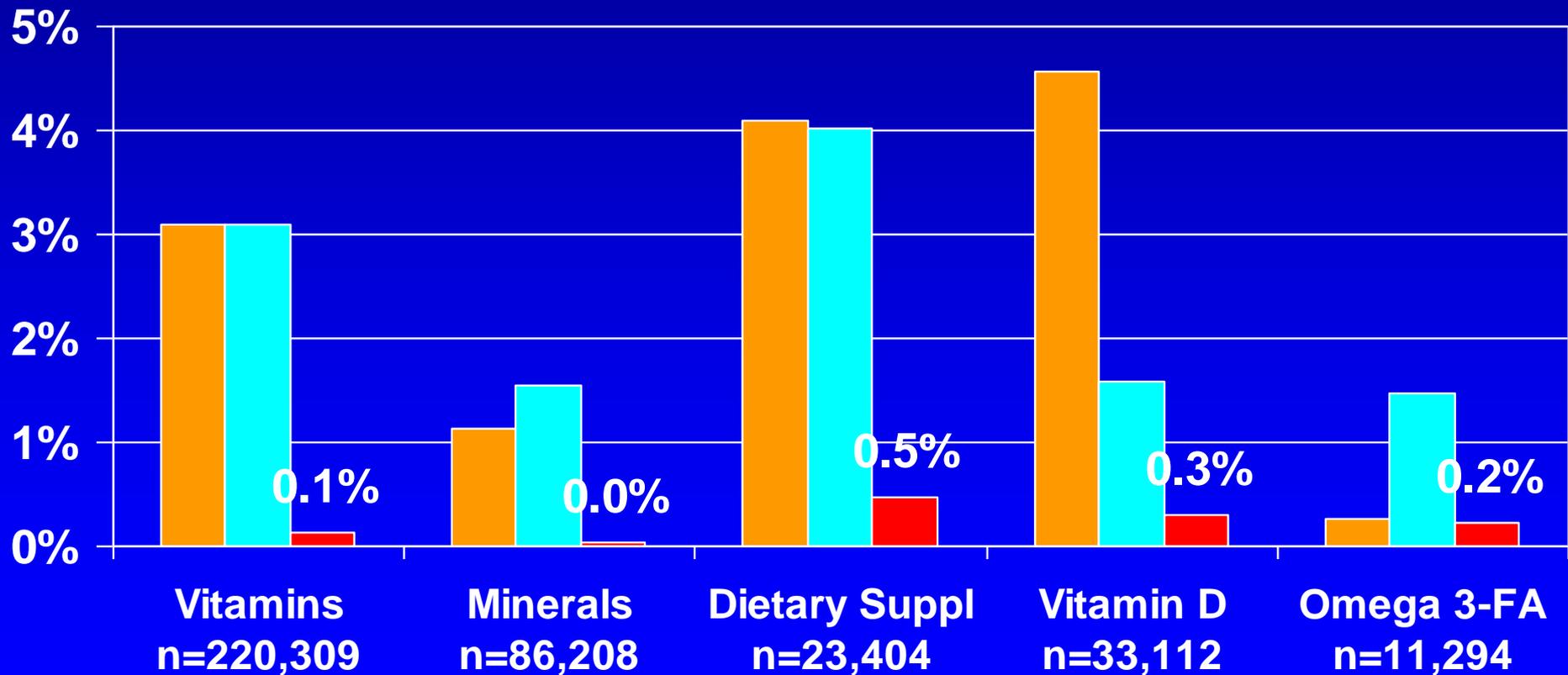
- Antioxidants and zinc in adults with intermediate-stage age-related macular degeneration reduced progression
- Some possible benefit of selenium, vitamin E, or both in cancer prevention, especially men
  - 2009 two negative trials
    - Selenium and Vitamin E Cancer Prevention Trial [SELECT]
    - Vitamin E and C Physicians' Health Study II

# Multivitamin/Mineral Supplements

- Few trials of individual or paired vitamins and minerals for the prevention of chronic disease produced beneficial effects
- No evidence to recommend  $\beta$ -carotene and strong evidence to avoid in smokers
- Calcium and vitamin D have a beneficial effect on bone mineral density and fracture risk in postmenopausal women
- Trials of niacin; folate; and vitamins B2, B6, and B12 produced no positive effect on chronic disease occurrence in the general population

# Potentially Relevant Publications

■ Prevention ■ Economic ■ Economic+Prevention



# Cost-effectiveness Registry

- Searchable database of >2000 cost-utility analyses of diseases and treatments
- Literature search → Screening → Data Abstraction → Data Cleaning & Processing → CEA Registry Database
- Cost-effectiveness ratios and utility weights

# Cost-effectiveness Registry

- 533,333 publications → 12 (2 / 100,000)
- Study quality (1 lowest to 7 highest)
  - 3.5 (2); 4 (5); 5 (4); 6 (1)
- Diseases
  - Osteoporosis/Fx (4); Macular degeneration (3); Heart disease (2); Neural tube defect
- Intervention
  - Vitamin D (4); Folate (4); Anti-oxidant (3); MVM (1)
  - Fortification (3); Primary Prevention (4)

“Essentially, all models are wrong, but some are useful.”

-George EP Box

“Our advice: Beware of geeks bearing formulas,

-Warren Buffet

# MAVIS Trial

- RCT of MVM in  $\geq 65$  y/o Scots
  - IRR primary care contacts = 1.07 (0.90-1.27)
  - IRR infection days = 0.966 (0.78-1.19)
- Cost-utility of MVM supplements
  - $\uparrow$   $\Delta$ Cost 15£ per person (-3.75-34.95)
  - $\downarrow$   $\Delta$  EQ-5D -0.18 (-0.04-0.002)

# Fortification

- Folic acid (140 µg) fortification and folic acid and cyanocobalamin supplements
  - Fortification 8-13% ↓MI
  - Suppl known CHD ↓310,000 deaths over 10 years
  - Suppl all men ≥45 and women ≥55: ↓300,000 deaths over 10 years ↓ \$2 billion
- Folic acid (140, 350 or 700 µg) fortification
  - ↓MI, Colon CA, NTD, ↑ masked B12 deficiency
  - ↑ 266,649 QALY and ↓ \$3.6 billion

# ODS and Legislation

- ODS created 1995 to meet the requirements of the Dietary Supplement Health and Education Act (DSHEA) of 1994
  - To explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care
  - To promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions

# ODS and Legislation

- DSHEA formal definition of “dietary supplement”
  - a product taken by mouth that contains a dietary ingredient, including vitamins, minerals, amino acids, herbs or botanicals, or other substances that can be used to supplement the diet
- May not make claims about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease unless it has approval to do so under the new drug provisions of the Federal Food, Drug and Cosmetics Act

# Supplementation and Fortification

- “Historically, fortification of foods has led to the remediation of vitamin and mineral deficits, but the cumulative effects of supplementation and fortification have also raised safety concerns about exceeding upper levels. Thus, there is a national need to improve the methods of obtaining accurate and current data on the public’s total intake of these nutrients in foods and dietary supplements.”

# Supplementation and Fortification

- “The current level of public assurance of the safety and quality of MVMs is inadequate, given the fact that manufacturers of these products are not required to report adverse events and the FDA has no regulatory authority to require labeling changes or to help inform the public of these issues and concerns. It is important that the FDA’s purview over these products be authorized and implemented.”

# Trading Regulations and Health Foods

- “The distinction between medicines and foods is sometimes unclear when they are marketed for health reasons, and consumers can be misled”
- “UK Joint Health Claims Initiative establishes a code of practice for health claims on food” with a systematic evidence process to assess safety and efficacy
- “All claims—such as ‘low fat,’ ‘high fibre,’ or ‘helps lower cholesterol’—are required to be clear, accurate, and substantiated, so that only products offering genuine health or nutritional benefits could refer to these claims on their labels”

# Conclusions

- Despite \$61 billion spent on MVM & fortification
  - insufficient evidence for or against MVMs for chronic disease prevention
  - Sparse economic studies
- Potential legislative, health policy and research investment implications
- “Make the most up-to-date scientific knowledge about dietary supplements publicly available.”