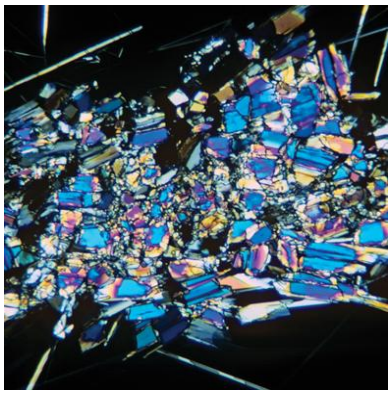
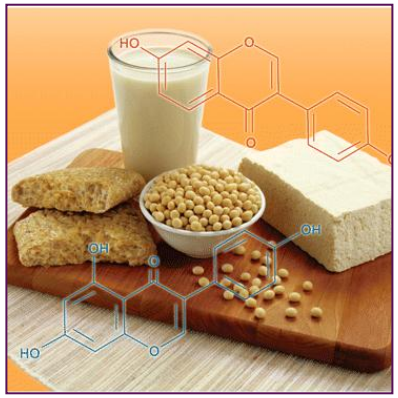




Economic Analyses of Nutrient Interventions for Chronic Disease Prevention



Paul M. Coates, Ph.D.
Director

Office of Dietary Supplements
National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Office of Dietary Supplements
National Institutes of Health

Overview

- What is the science telling us about effectiveness and cost-effectiveness of dietary supplements?
  - Evidence for their importance in health
  - Scientific gaps: What are the key issues?

- Challenges and strategies to address them
  - Key partners /stakeholders and their roles

Origin and Mission

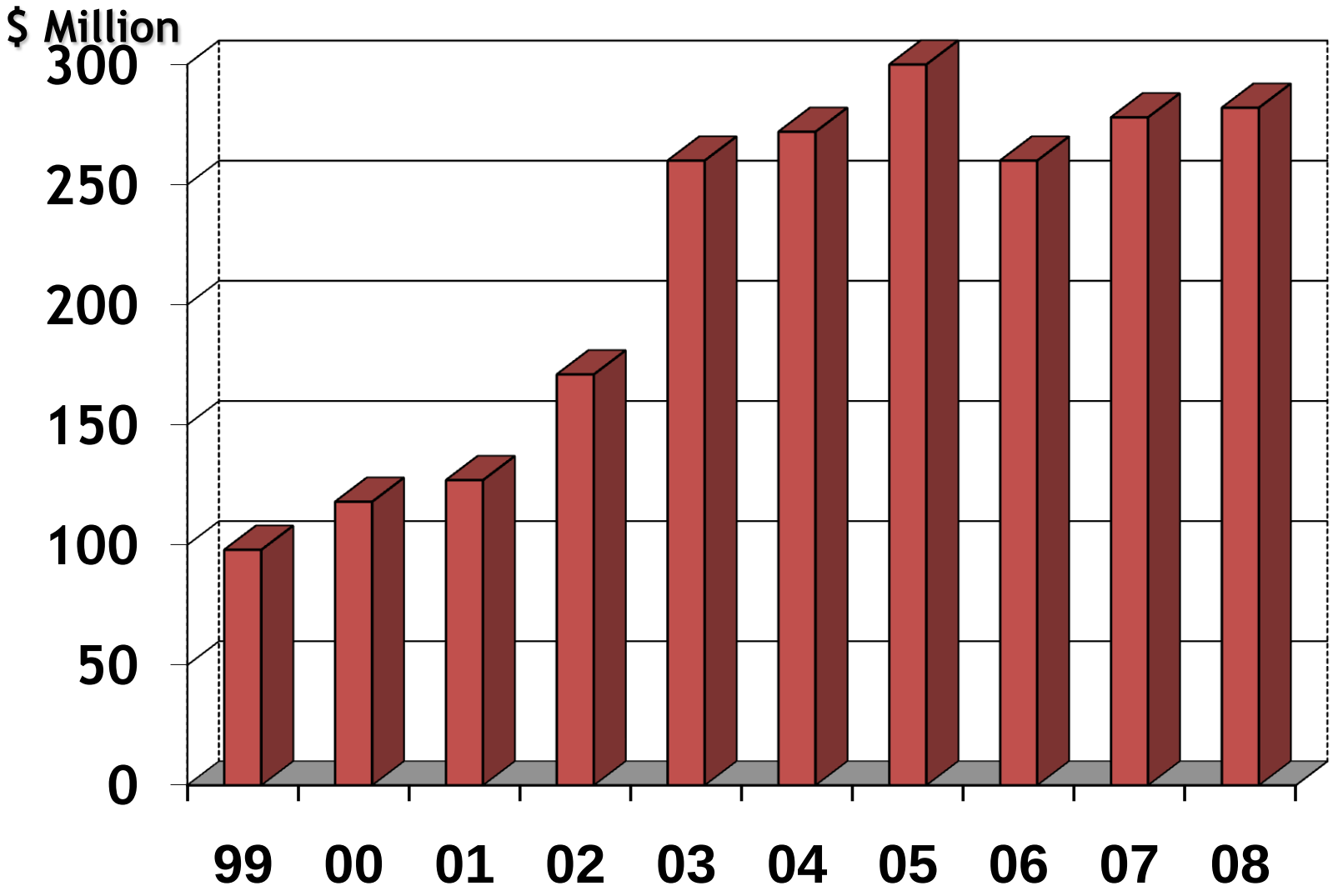
Office of
Dietary Supplements
National Institutes of Health

- The Dietary Supplement Health and Education Act (DSHEA) of 1994 authorized the establishment of the ODS at the NIH.

- Mission: Strengthen knowledge and understanding of dietary supplements to foster an enhanced quality of life and health for the U.S. population by
    - Evaluating scientific information
    - Stimulating and supporting research
    - Disseminating research results
    - Educating the public.

Public Law 103-417, DSHEA

Overall NIH Funding for Dietary Supplement Research



ODS Focus

Efficacy

Quality

Safety

ODS Evidence-Based Review Program

- Systematic review of the literature, with meta-analysis as appropriate, on DS efficacy and safety
- Collaboration with the Agency for Healthcare Research and Quality Evidence-Based Practice Center Network
- Major reason for conducting these reviews is to assist NIH in the development of research agendas
- Examples (partners): ephedra (NCCAM, FDA), omega-3 fatty acids (multiple), soy (NCCAM), probiotics (NCCAM, FDA), vitamin D

Dietary Supplement Research Product Concerns

- Identification
- Characterization
- Reproducibility

Dietary Supplement Research Protocol Concerns

- Populations (Generalizability)
- Endpoints
- Doses
- Earlier Phase Studies

Issues

Office of
Dietary Supplements
National Institutes of Health

- ODS and its partners are interested in evaluating the efficacy of dietary supplements.
- This logically leads to questions of effectiveness (i.e., “real world” demonstration)……
- And then on to cost-effectiveness (i.e., what are the costs, assuming a benefit) of dietary supplement interventions.
- These turn out to be somewhat charged questions.
  - What is efficacy?
  - Effective compared to what?
  - How are costs computed?

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

Office of Dietary Supplements
National Institutes of Health

- ODS, NCCAM, NCI, and NINR sponsored this workshop in Feb 2010.
- Background:
  - Increasing healthcare expenditures
  - Nutrition (including dietary supplements) in chronic disease prevention
- State of the science:
  - Health economic methods used to judge burden of illness, interventions, and healthcare policies
  - What new methodologies are becoming available or are needed?
- What are the current and planned evidence-based health economic research activities at US federal agencies?
  - What is being or can be applied to nutrition interventions?

NIH-Sponsored Trials

- Generally, single-ingredient intervention trials, in high-risk subjects, against placebo, with clinical endpoints (e.g., omega-3 fatty acids for prevention of cardiovascular disease recurrence; selenium for prevention of prostate cancer in subjects with benign prostatic hyperplasia).
- Based on observational studies pointing to relationship between exposure to a nutrient (or group of nutrients) and health benefits and/or pre-clinical studies, but these cannot be used as proof that health benefit was caused by exposure.
- Generally, little or no health effect, positive or negative.
  - Exceptions, e.g., vitamin D and calcium; AREDS
- Limitations
  - Observational studies: contamination of groups, inability to eliminate confounding
  - Interventional studies: trial design (duration, dose), generalizability

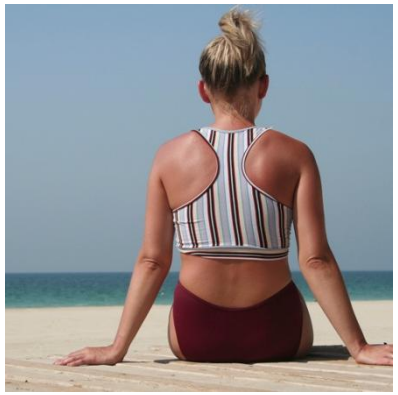
Concerns

- Absent demonstrable efficacy, it becomes very difficult to assess effectiveness
- Some attempts, but analyses limited by data and conclusions limited by assumptions
  - Chromium/biotin and diabetes
  - Omega-3s and CVD
- Others rely on relating epi data on use of supplements (e.g., MVM) and costs of illness
  - Modeling exercises
  - Fail to provide estimates of error

Systematic Reviews of Vitamin D and Health Outcomes

- Agency for Healthcare Research and Quality (AHRQ)
  - Evidence-Based Practice Center Network (www.ahrq.gov/clinic/epc)
  - Systematic reviews inform policy, research, guidelines
- Two Reviews of Vitamin D
  - Cranney A et al: Am J Clin Nutr 88:513S-519S, 2008
    - Sponsored by ODS to inform research agenda
  - Chung M et al: Am J Clin Nutr 92:273-276, 2010
    - Sponsored by U.S. and Canadian governments to inform deliberations of Dietary Reference Intakes Panel of the Institute of Medicine

Findings from the First Systematic Review



- Evidence that vitamin D supplementation reduces falls, fractures, and bone loss in men and women >60 years
- Sparse data on other age and gender groups
- Not possible to separate the effect of vitamin D from Ca supplementation
  - Typical amounts used were 700-800 IU vitamin D/day and 500-1,200 mg Ca/day
- Difficult to identify a specific blood level of 25-hydroxyvitamin D indicative of optimal bone health in all population subgroups: Lack of data

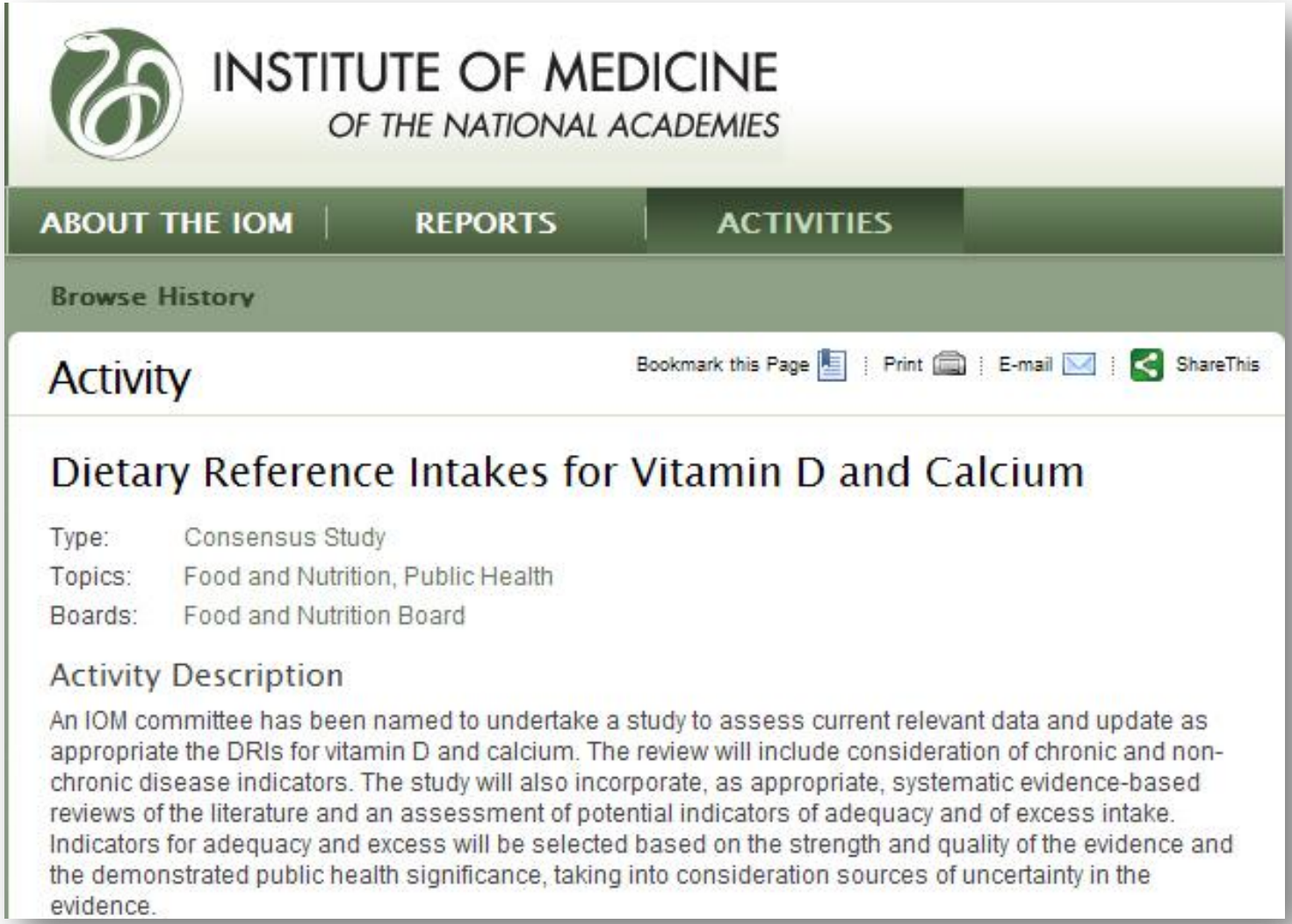
Cranney A et al: Am J Clin Nutr 88:513S-519S,2008

Findings from the Second Systematic Review

- Infant growth: Most studies find no effect
- Cardiovascular disease
  - Randomized controlled trials: No effect
  - Cohort studies: Variable association
- Body weight: No effect
- Cancer: No effect
- Infectious diseases: No effect
- Pregnancy outcomes: Inadequate data
- All-cause mortality: Inconsistent data
- Hypertension: Inconsistent data

Chung M et al: Am J Clin Nutr 92:273-276, 2010

IOM Review of Dietary Reference Intakes



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

ABOUT THE IOM | REPORTS | ACTIVITIES

Browse History

Activity

Bookmark this Page | Print | E-mail | ShareThis

Dietary Reference Intakes for Vitamin D and Calcium

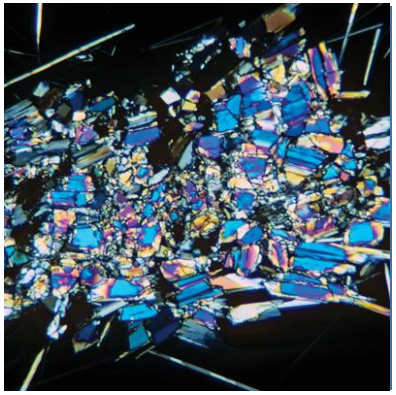
Type: Consensus Study
Topics: Food and Nutrition, Public Health
Boards: Food and Nutrition Board

Activity Description

An IOM committee has been named to undertake a study to assess current relevant data and update as appropriate the DRIs for vitamin D and calcium. The review will include consideration of chronic and non-chronic disease indicators. The study will also incorporate, as appropriate, systematic evidence-based reviews of the literature and an assessment of potential indicators of adequacy and of excess intake. Indicators for adequacy and excess will be selected based on the strength and quality of the evidence and the demonstrated public health significance, taking into consideration sources of uncertainty in the evidence.

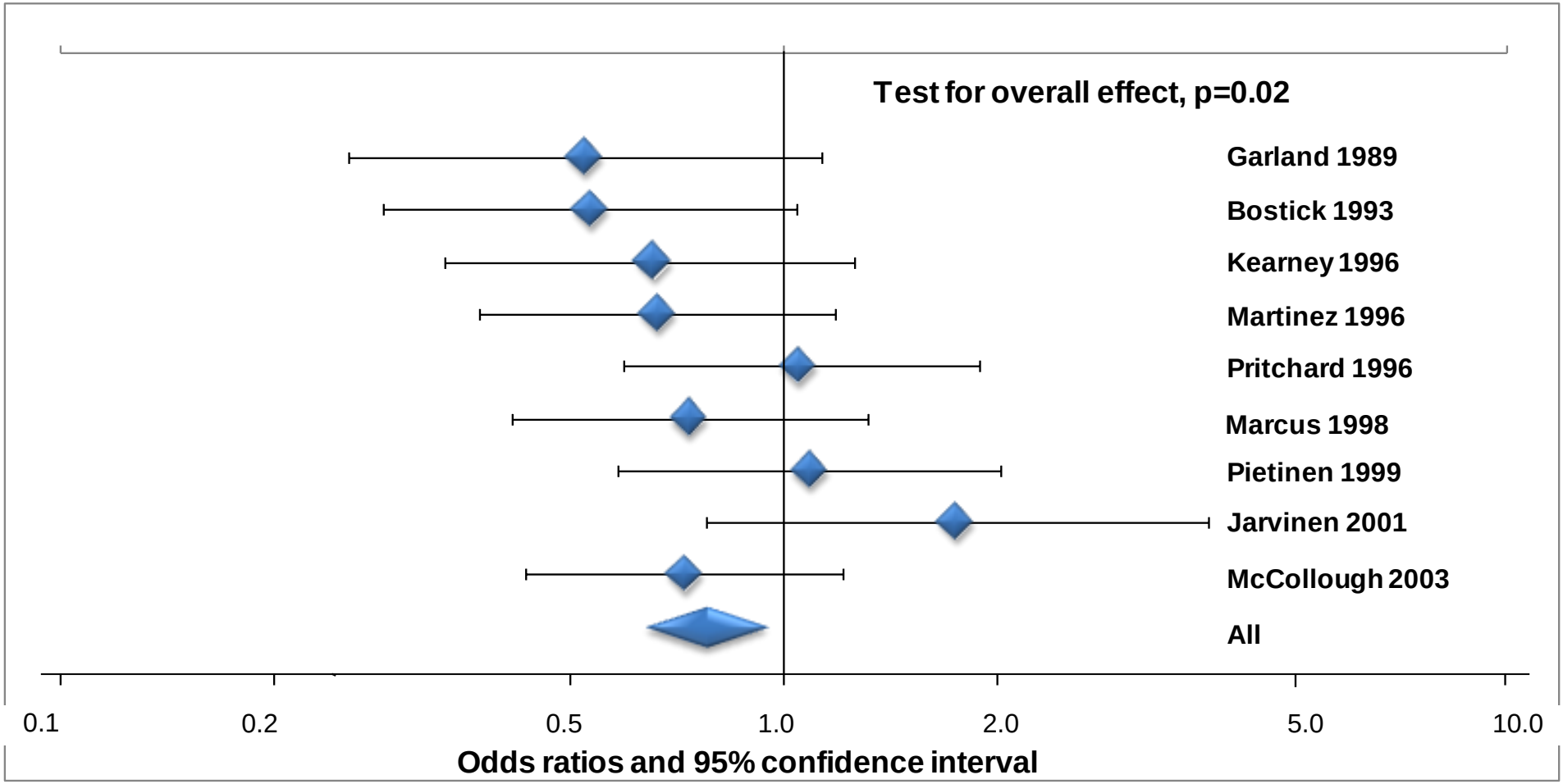
www.iom.edu/Activities/Nutrition/DRIVitDCalcium.aspx

Vitamin D Challenges



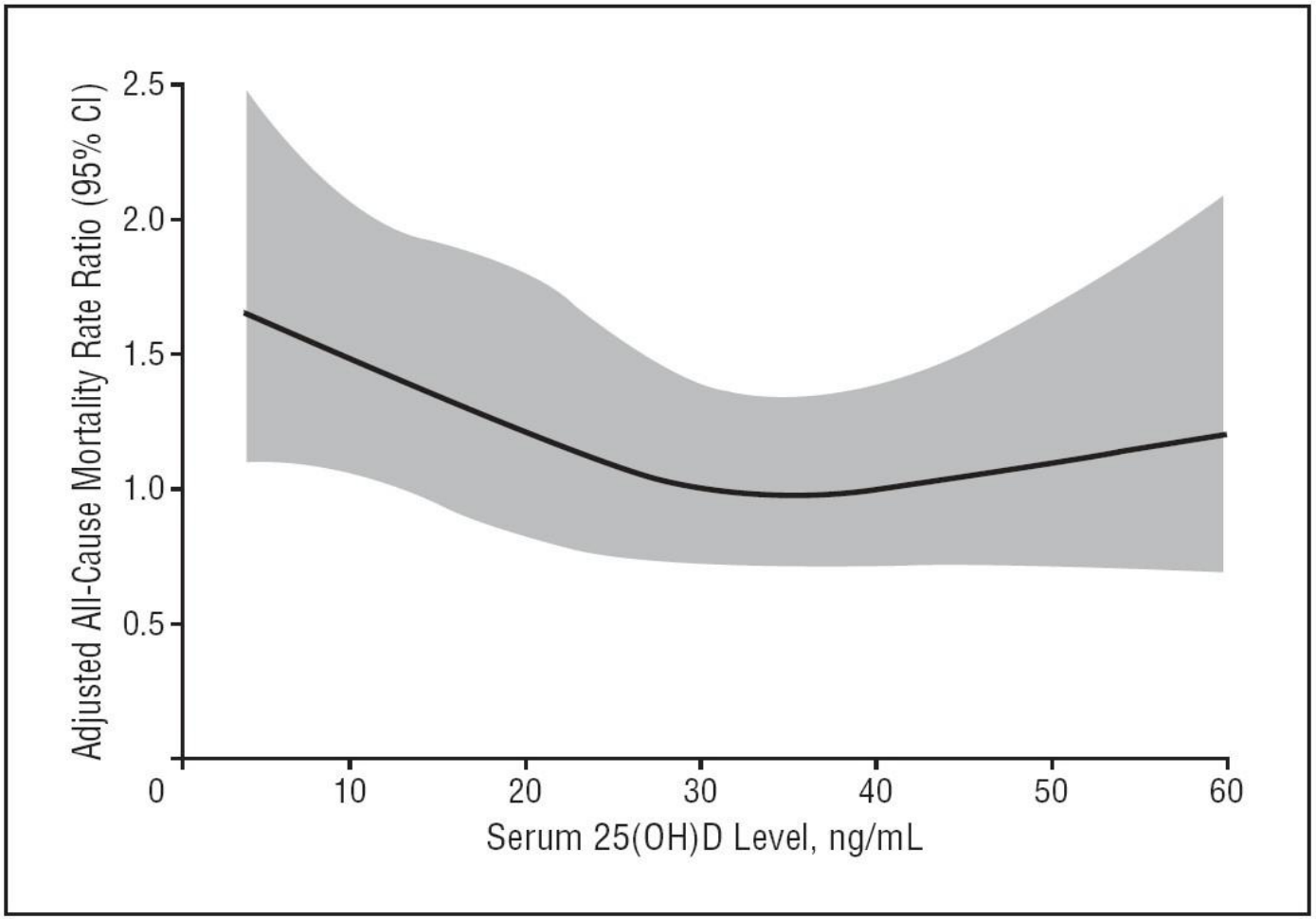
- Exposure
  - UV exposure
  - Foods, including fortified foods
  - Dietary supplements
- Health outcomes
  - Enormous interest based on case reports, observational studies
  - Inconsistent findings from controlled studies, except for elderly
  - Safety must be addressed
- Measurement of status
  - Potential for incorrect interpretation, especially when assessing trends over time

Vitamin D and Colorectal Cancer



Wei MY et al,.Cancer Epidemiol Biomarkers Prev 17:2958-2969, 2008

Serum 25(OH)D and All-Cause Mortality



Melamed et al. Arch Intern Med 2008;168:1629-1637

Future Needs

- Continued monitoring of status to assess impact of public health recommendations for vitamin D intake
- Dose-response relationships
- Research into basic mechanisms
- Ongoing partnerships among agencies in US and Canada: CDC, NIH, NIST, USDA and Health Canada

Office of Dietary Supplements
National Institutes of Health

www.ods.od.nih.gov