

Nutritional Supplements

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Objectives

At the completion of this lecture, the student will be able to:

- Define & identify nutritional supplements.
- Be aware of common nutritional supplement usage.
- List the major provisions of the Dietary Supplement Health and Education Act of 1994 (DSHEA).
- Evaluate claims and safety issues for supplements and supplement use by patients.
- Determine when the use of nutritional supplements is / isn't indicated.

Suggested Reading

- Chapters 2 and 3 in: Medical Nutrition & Disease, Hark L, Morrison G, eds, 3rd edition, Blackwell Publishing, Malden, MA, 2003.
- Position of the American Dietetic Association: Food fortification and dietary supplements. *J Am Diet Assoc.* 2001;101:115-125. (on reserve at library)
- Fletcher RH, Fairfield KM. Vitamins for Chronic Disease Prevention in Adults: Clinical Applications. *JAMA.* 2002;287:3127-3129. (on reserve at library)
- Rosenberg I. Vitamins and Minerals: Safe at any Dose? *Nutr Clin Care.* 2001;67-69. (on reserve at library)
- Fontanarosa PB, Rennie D, DeAngelis CD. The Need for Regulation of Dietary Supplements: Lessons from Ephedra. *JAMA.* 2003;289:1568-1570. (on reserve at library)

Other Resources

- National Institutes of Health Office of Dietary Supplements <http://odp.od.nih.gov/ods>
- U.S. Food & Drug Administration warnings- <http://www.cfsan.fda.gov/~dms/ds-warn.html>
- National Center of Complementary and Alternative Medicine- <http://nccam.nih.gov/>

Dietary Supplement Defined

A product intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

A vitamin; A mineral; An herb or botanical; An amino acid; A dietary substance used to supplement the diet by increasing the total dietary intake; A concentrate, metabolite, enzyme, constituent, extract; or A combination of any ingredients described above.

Dietary Supplement Health and Education Act (DSHEA) of 1994

- A. Defined dietary supplements: not drugs
- B. Placed responsibility for safety on manufacturers.
 1. Manufacturers must use good manufacturing practices.
 2. But, unlike drugs approved by FDA, product may be marketed without any review process and the burden of proof for problems is on FDA.
- C. Specified types of statements that can be used on dietary supplement labels.
 3. Nutrient content claims
 4. Structure/function claims
 5. Health claims
- D. Identified how literature may be used in conjunction with sales of dietary supplements.

E. Created the Office of Dietary Supplements (ODS) under the auspices of NIH.

Vitamins Defined: an organic compound that is essential in small amounts for control of metabolic processes and that cannot be synthesized by human tissue cells with simple metabolites

Minerals Defined: an inorganic substance, occurring in nature

Macrominerals- essential at >100 grams/day: Calcium, Chloride, Magnesium, Phosphorus, Potassium Sodium, Sulfur.

Microminerals- essential at a few milligrams/day: Arsenic, Boron, Chromium, Copper, Fluoride, Iodine, Iron, Manganese, Molybdenum, Nickel, Selenium, Silicon, Vanadium, Zinc

When should dietary supplements be used?

- A. Key point- relying on a balanced diet is usually the best strategy for optimal nourishment.
 - 1. Need to avoid excesses and imbalances, as well as insufficiencies.
 - 2. Some food components with potential benefits are not easily incorporated into supplements.
 - 3. Much remains unknown about biologically active components in food.
 - 4. Combinations of substances or the matrix in which nutrients appear may also be important.
- B. Dietary supplements are appropriately used under two conditions:
 - 1. To optimize cellular function.
 - a. Dietary intake is inadequate.
 - b. Physiological need, ie, requirements are increased, abnormal absorption, or excessive losses
 - 2. To obtain a pharmacologic effect to correct abnormal cell function due to a disease process.

Multivitamins/minerals

- A. Claims- who may benefit?
 - 1. Most people use MVIs as “insurance” for a marginal diet
 - 2. Pregnant women, older adults, children, teens, persons with certain chronic diseases, persons on weight loss or low calorie diets, gastric bypass patients, patients with burns or wounds, malnourished patients
- 1. Cautions- how to pick an MVT
 - a. Look for 100% of RDA or AI, while not exceeding the UL
 - b. “There is no established benefit for healthy individuals if they consume a nutrient in amounts above the recommended intake (RDA or AI).”
 - c. Preformed vitamin A should not be taken in the first trimester of pregnancy.
 - d. Men and postmenopausal women should not take supplemental iron without a clinical assessment indicating low iron status.
- B. Antioxidant vitamins (β -carotene, vitamin C, vitamin E)
 - 1. Evidence
 - a. Based on epidemiological data, the more dietary antioxidants consumed within a population, the lower the rate of heart disease and death.
 - b. Cohort studies show promising results, but may be biased by participant selection and confounding factors.
 - c. Clinical trials have been disappointing

Supplements to be familiar with:

Vitamin A, Vitamin C, Vitamin E, Folate, Calcium, Magnesium, Iron, Zinc,
Common Herbals and Botanicals: ginkgo-biloba, black cohosh, cartilage, coenzyme Q10, ephedra, garlic, green tea, milk thistle, St. John’s wort, valerian root

Considerations in Recommending Dietary Supplement Use to Patients

A. The Position of the American Dietetic Association:

“... the best nutritional strategy for promoting optimal health and reducing the risk of chronic disease is to choose wisely from a wide variety of foods. Additional vitamins and minerals from fortified foods and/or supplements can help some people meet their nutritional needs as specified by science-based nutrition standards such as the Dietary Reference Intakes (DRI).”

B. Ethical considerations

1. Have I sufficiently researched this product to comment on it or should I refer?
2. Am I familiar with dosages and potential interactions with drugs?
3. Am I convinced of the safety and efficacy of the product?
4. Is there enough scientific evidence that potential benefits outweigh potential risks?

C. Refer to AMA Ethics Committee report

American Medical Association Council on Ethical and Judicial Affairs. *Sale of health-related products from physicians' offices*. CEJA Opinion 8.063. Available at: <http://www.ama-assn.org/ethic/ceja/webprt.htm>; June, 1999.

Case Study

A 66-year-old man, with a history of myocardial infarction (MI) and successful coronary artery bypass surgery (CABG), is seen in your office for routine follow-up. He seems to be very highly motivated to make lifestyle changes and reports changing to a low-fat diet and adding some nutritional supplements to his daily regimen. He wants to know your opinion about the supplements he is taking. His current medications are:

- Mevacor (lovastatin) (20 mg HS)
- Aspirin (acetylsalicylic acid) (325 mg q d)
- Tenormin (atenolol) (25 mg q d)
- Zestril (lisinopril) (10 mg q d)
- Coenzyme Q10 (ubiquinone) (100 mg q d)
- Vitamin E (dl- α -tocopherol) (800 IU BID)
- One-A Day for Men[®]

Questions:

1. Which of the “medications” that he is taking are nutritional supplements?
2. Do any of these supplements have side effects that might be problematic for this patient?
3. If you need more information, where would you look?
4. What recommendations would you make to this patient?

Key points to consider: is CoQ10 indicated in his condition and is the dose of CoQ10 appropriate? Is vitamin E indicated and is the dose appropriate? Is there vitamin E already in the MVI preparation he is taking and how much? Are there any nutrient-drug interactions to be considered?

Take Home Points

- Know the definition of “dietary supplement,” “vitamin,” and “mineral;”
- Know common nutritional supplements & usage;
- Know the major provisions of DSHEA;
- Describe the claims on the supplement label;
- Know potential indications, recommendations, and hazards for common nutritional supplements.

Sample Test Questions

1. Which of the following products are covered under DSHEA?
 - a. Multivitamin / minerals (e.g. Centrum®, One A Day®)
 - b. Digestion enhancers (e.g. Lactaid®, Beano®)
 - c. Performance enhancers (e.g. Ripped Fuel®, Ultimate Orange®)
 - d. Weight loss formulas (e.g. Metabolife®, Accutrim®)
 - i a only
 - ii a and b
 - iii a, b, d
 - iv a, c, d
 - v All of the above
2. Supplemental intake of which of the following vitamins is generally not advisable?
 - a. Vitamin E
 - b. Vitamin A
 - c. Vitamin C
 - d. Vitamin D
3. When discussing the use dietary supplements with patients, what is the best approach?
 - a. “Don’t ask, don’t tell.”
 - b. Make recommendations based on personal experience with the supplement in question.
 - c. If unfamiliar with the supplement in question, make a referral to a registered dietitian.
 - d. Discourage the use of all dietary supplements.
4. Which claim is not allowed by DSHEA?
 - a. “this product is high in fiber”
 - b. “this product helps maintain normal cholesterol levels”
 - c. “this product may reduce your risk for heart disease”
 - d. “this product prevents Alzheimer’s disease”

Answers

1. iv. a, c, d
2. b.
3. c.
4. d.

Selected References

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