

As healthcare providers, we are seeing many clients either already taking dietary supplements or inquiring whether or not they *should* be on them.

More women than men use supplements, and older adults are more likely than younger adults to use them. Supplement usage in the United States generates greater than \$30 billion a year in sales.

Today's dietary supplements are not only vitamins and minerals, they also include herbals and botanicals, amino acids, enzymes, and many other products. Dietary supplements come in a variety of forms: traditional tablets, capsules, and powders, as well as drinks and energy bars. Popular supplements include vitamins D and E; minerals like calcium and iron; herbs such as echinacea and garlic; and specialty products like glucosamine, probiotics, and fish oils. Whatever the choice, healthcare providers should stress to clients that supplements shouldn't replace the variety of foods important to a healthful diet. Our clients need guidance in knowing what they are taking, why they are taking it, and how to do so safely.

It's important to know that unlike prescription and over-the-counter drugs, dietary supplements are not pre-approved by the government for safety or effectiveness before marketing. Also, unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. Some supplements can help assure that individuals get an adequate dietary intake of essential nutrients; while others may help reduce overall risk of disease. Some older people, for example, are tired due to low iron levels. In that case, the healthcare team (to include the physician) may recommend or order an iron supplement.

What is a Dietary Supplement?

The Food and Drug Administration (FDA) defines "dietary supplement" as any product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. Dietary ingredients may include such things as vitamins, minerals, herbs or other botanicals, amino acids, enzymes, extracts, and concentrates. Products that fall into the dietary supplement category include everything from multi-vitamins to fish oil, many weight loss products, and formulas to relieve menopausal symptoms. A dietary supplement is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a dietary supplement.

Are Dietary Supplements Different from Foods and Drugs?

Although dietary supplements are regulated by the FDA as foods, they are regulated differently from other foods and from drugs. Whether a product is classified as a dietary supplement, conventional food, or drug is based on its intended use.

What Claims Can Manufacturers Make for Dietary Supplements and Drugs?

The types of claims that can be made on the labels of dietary supplements and drugs differ. Drug manufacturers may claim that their product will diagnose, cure, mitigate, treat, or prevent a disease. Such claims may not legally be made for dietary supplements.

The label of a dietary supplement or food product may contain one of three types of claims: a health claim, nutrient content claim, or structure/function claim. Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product. A structure/function claim is a statement describing how a product may affect the organs or systems of the body, and it cannot mention any specific disease. Structure/function claims do not require FDA approval, but the manufacturer must provide FDA with the text of the claim within 30 days of putting the product on the market. Product labels containing such claims must also include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

Why Should You Take the Time to Read and Understand the Labels?

Many people assume that anything "natural" is automatically safe and good for you. Keep in mind that some natural things can be harmful and potentially poisonous. Even certain vitamins can be toxic at high dosages.

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Figure 1

Some dietary supplements may also have drug-like effects. They could have an unsafe interaction with a prescription your client may be taking, or they may aggravate a health condition. For example, vitamin K can reduce the ability of prescription blood thinners to prevent blood clots. St. John’s wort may reduce the effectiveness of anti-depressants and birth control pills. Manufacturers are not required to test for potential prescription drug interactions.

The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. The FDA steps in, for example, if it’s determined that it carries an unreasonable health risk or that it is adulterated with ingredients not listed on the label.

Good Manufacturing Practices (GMP): Good News for Consumers

Federal law requires that dietary supplement manufacturers comply with current Good Manufacturing Practices (GMP). GMP compliance, which is monitored and enforced by the FDA, regulates a product’s identity, strength, purity, and composition. While GMP does not guarantee product safety or effectiveness, it is your assurance that a product contains what it says on the label, and does not contain harmful levels of contaminants or impurities.

In addition, three independent organizations offer GMP quality testing. Products that pass these tests are allowed to display the organization’s seal of approval on their labels. These organizations are:

- U.S. Pharmacopeia (labeled as USP) www.usp.org
- ConsumerLab.com (labeled as CL)
- NSF International (labeled as NSF) www.nsf.org

Other Labeling Information

All dietary supplement ingredients must be printed on the label, either under Supplement Facts or Other Ingredients. In addition, the label should disclose whether the product contains any common allergens such as wheat or gluten. There should also be contact information for the manufacturer or distributor, a lot number for traceability, and an expiration date to ensure full potency.

The Supplement Facts Panel will indicate the serving size, suggested use (For adults only/Take with or without food),

Supplement Facts	
Serving Size: 1 Capsule	
Amount Per Capsule	% Daily Value*
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

and storage suggestions. The amount per serving of all active ingredients/nutrients, as well as the percent of recommended daily intake (if established) of those ingredients is included. If there are no recommended intake guidelines established, you will see an asterisk.

Those percentages could be important. For example, an individual taking a multi-vitamin and eating vitamin-fortified cereals daily, along with a dietary supplement formula that also contains vitamins, may push the daily intake of certain vitamins or minerals into unsafe levels. Anything else in the supplement, including fillers and ingredients used to maintain the product’s stability, must be listed under Other Ingredients. Those will be listed by weight, in decreasing order. See Figure 1.

What About Vitamin, Mineral, and Multivitamin Supplements for the Primary Prevention of Cardiovascular Disease and Cancer?

Most vitamins and mineral supplements, alone or in combination, have not proved to help or hurt when it comes to preventing cancer or heart disease, according to a report from the high profile U.S. Preventive Services Task Force (USPSTF) in their final recommendation statement on Vitamin, Mineral, and Multivitamin Supplements for the Primary Prevention of Cardiovascular Disease and Cancer.

Answers to Nutrition Connection Questions

CDMs who answer the Nutrition Connection Questions on page 28 of this issue can check their responses against the answer key found on page 39. This "self check" allows you to confirm your understanding of the test questions.

This final recommendation statement applies to healthy adults who have no known nutritional deficiencies. It does *not* apply to women who are pregnant, women who may become pregnant, or to adults who are in the hospital. The Task Force recommends that adults being treated for a long-term illness should talk with their healthcare professional about whether this recommendation applies to them.

The final recommendation statement includes a summary of what the Task Force learned about the potential benefits and harms of taking vitamin and mineral supplements to prevent cardiovascular disease (CVD, which includes heart disease and stroke) and cancer:

- 1) Currently, there is not enough evidence to determine whether taking a multivitamin will help prevent CVD or cancer.
- 2) There is not enough evidence to determine whether taking most single or paired supplements will help prevent CVD or cancer.

- 3) Taking vitamin E or beta carotene supplements does not help prevent CVD or cancer, and beta-carotene supplements may increase the chance of getting lung cancer for people who are already at risk of lung cancer, such as smokers.

Recommendations of Others

An independent consensus panel sponsored by the National Institutes of Health concluded that the present evidence is insufficient to recommend for or against the use of multivitamins to prevent chronic disease. The Academy of Nutrition and Dietetics (formerly the American Dietetic Association) noted in a 2009 position statement that, although multivitamin supplements may be useful in meeting the recommended levels of some nutrients, there is no evidence that they are effective in preventing chronic disease. The American Cancer Society found that current evidence does not support the use of

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dietary supplements for the prevention of cancer. The American Institute for Cancer Research determined in 2007 that dietary supplements are not recommended for cancer prevention, and recommended a balanced diet with a variety of foods rather than supplements. The American Heart Association recommends that healthy persons receive adequate nutrients by eating a variety of foods rather than supplementation. The American Academy of Family Physicians' clinical recommendations are consistent with the USPSTF recommendations.

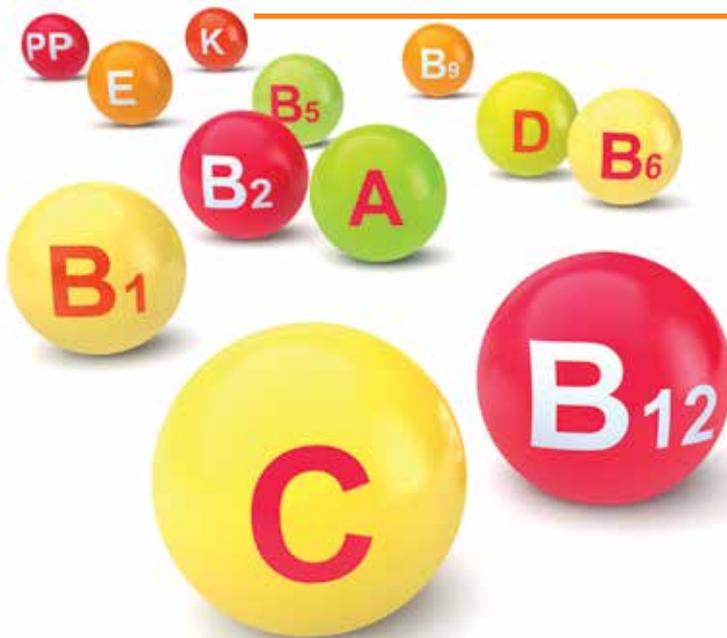
Regulatory Guidelines

Guidelines for use of dietary supplements are included in several regulatory resources used in long-term care. The Centers for Medicare and Medicaid Services (CMS) instructs surveyors to use "best practice" guidelines developed by professional organizations to determine compliance with specific regulations.

nutritional goals for the whole person. A simple multivitamin is appropriate, but unless the resident has a specific vitamin or mineral deficiency, supplementation with additional vitamins or minerals may not be indicated.

Additional strategies for wound healing may be considered when indicated. A multivitamin/mineral supplement may be prescribed, however current evidence does not definitively support any specific dietary supplementation (e.g., Vitamin C and Zinc) unless the resident has a specific vitamin or mineral deficiency.

In the Resident Assessment Instrument (RAI) Manual, the Minimum Data Set (MDS) coding tips in Chapter 3 (MDS Item N0410) for herbal and alternative medications state that:



Although multivitamin supplements may be useful in meeting the recommended levels of some nutrients, there is no evidence that they are effective in preventing chronic disease.

—The Academy of Nutrition and Dietetics

In the State Operations Manual (SOM) Appendix PP Guidance to Surveyors for F314 Pressure Sores and Under-Nutrition and Hydration Deficits, the following statement is included:

Before instituting a nutritional care plan, it helps to summarize resident-specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual's prognosis and projected clinical course, and the resident's wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop

Received Herbal and alternative medicine products are considered to be dietary supplements by the Food and Drug Administration (FDA). These products are not regulated by the FDA (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). Therefore, they should not be counted as medications (e.g. chamomile, valerian root). Keep in mind that, for clinical purposes, it is important to document a resident's intake of such herbal and alternative medicine products elsewhere in the medical record and to monitor their potential effects as they can interact with medications the resident is currently taking. For more information consult the FDA website at <http://www.fda.gov/food/dietarysupplements/consumerinformation/ucm110567.htm>

These substances may be coded at the MDS Item K5f provided they meet the definition of dietary supplement for this Item.” More information on dietary supplements identified by the FDA can be found at the following website: <http://health.nih.gov/>. Vitamins are considered medications, however other products may be considered supplements.

In Section K of the RAI manual there are MDS Coding Tips for K0510D for *Nutritional Approaches: Therapeutic Diet*.

- *Therapeutic diets are not defined by the content of what is provided or when it is served, but why the diet is required. Therapeutic diets provide the corresponding treatment that addresses a particular disease or clinical condition which is manifesting an altered nutritional status by providing the specific nutritional requirements to remedy the alteration.*
- *A nutritional supplement (house supplement or packaged) given as part of the treatment for a clinical condition manifesting an altered nutrition status, does not constitute a therapeutic diet, but may be part of a therapeutic diet. Therefore, supplements (whether given with, in-between, or instead of meals) are only coded in K0510D, Therapeutic Diet when they are being administered as part of a therapeutic diet to manage problematic health conditions (e.g. supplement for protein-calorie malnutrition).*



New ANFP Online Course Focuses on Medical Terminology and Drug-Nutrient Interactions

ANFP's new **Medical Terminology and Drug-Nutrient Interactions** online course delivers 20 hours of CE.

If your job responsibilities include clinical nutrition care, this course is for you! You'll learn how to read the daily language of medicine in medical records and on care plans. You'll build a working vocabulary of terms related to body systems, medical conditions, tests, treatments, and surgeries. You'll also learn that some food and drugs just don't mix and how that impacts the health and care of the client.

View course description and order at www.ANFPonline.org/market

Tips for Using Dietary Supplements

When working with clients the following tips may help:

- Always follow the suggested serving size listed on the label. Taking more than the recommended amount may jeopardize their health.
- If they are taking a dietary supplement for a specific purpose, for example to support heart health, consistency matters. Taking a supplement now and then won't give them the same benefits as taking it daily.
- Instruct the client to work with healthcare professionals to help them in selecting an ingredient or formula that actually does what it is supposed to do and in their decisions regarding use of dietary supplements, to make sure they are making informed decisions regarding their overall health.

Final Thoughts

As healthcare providers, we can be a valuable resource to help our clients with decisions about use of dietary supplements. The primary message we should all share is that taking supplements should never be considered a substitute for a healthy diet. Essential nutrients from real foods like fresh fruits, vegetables, lean meats, dairy products, and whole-grains cannot easily be provided by a few pills. Those are just – well, supplements. ☺

References

National Institute of Health, Office of Dietary Supplements, website (accessed 3/2/2014),

<http://ods.od.nih.gov/HealthInformation/makingdecisions.sec.aspx>

U.S. Preventive Services Task Force, <http://www.uspreventiveservicestaskforce.org/uspstf14/vitasupp/vitasupfinalrs.htm>

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*, Vitamin, Mineral, and Multivitamin Supplements for the Primary Prevention of Cardiovascular Disease and Cancer: U.S. Preventive Services Task Force Recommendation Statement, Published online at www.annals.org on 25 February 2014.

Additional Resources

National Institutes of Health: The NIH supports research on dietary supplements.

- Office of Dietary Supplements: <http://ods.od.nih.gov/>
- National Center for Complementary and Alternative Medicine: <http://nccam.nih.gov/>
- National Library of Medicine: <https://www.nlm.nih.gov/>
> Medline Plus
> PubMed
- U.S. Food and Drug Administration:
> <http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110567.htm>