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INTRODUCTION

Nutrition and diet are categorized by the National Center for Complementary and Altemative Medicine (NCCAM) as forms of Complementary and Alternative Medicine (CAM) under the categories of "Alternative Medical Systems" and "Biological Based Therapies."1 They are considered CAM by following the definition in which CAM is treatments and health care practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies.2 While in fact general principles of nutrition and diet are considered to be in the mainstream of practice.

Diet is a cornerstone of disease prevention and management. The landmark studies on diabetes,3 hypertension,4 and other diseases have provided scientific evidence of the value of diet and nutrition in disease prevention and management. Dietary supplements,functional foods and phytochemicals,are also considered CAM therapies (under the biologically based therapies), and are intended to 'supplement,' not replace foods in the diet.

The purpose of this article is to describe the fundamental principles of a healthful diet, dietary supplements (including herbs and botanicals) and functional foods with a focus on soy protein and phytochemicals. Basic principles for interviewing and educating patients regarding nutrition and diet (both mainstream and complementary) will also be presented.

FUNDAMENTAL PRINCIPALS OF A HEALTHFUL DIET

While spending on dietary supplements was at a record high of $3.38 billion per/year at the end of the 20th century,5 Americans concern for the healthfulness of their diet was at one of its lowest points. Consumers and professionals consistently cite the challenge of eating a 'healthful' diet, adequate in all

nutrients, as time consuming and difficult.6 There are no 'good' or 'bad' foods rather all foods can fit into a healthful lifestyle if the diet provides moderation and variety. Moderation in serving sizes and frequency of eating and variety in selection of foods from all food groups in the food guide pyramid. Selection of foods from all groups in amounts to meet each individuals needs is the best strategy for any diet, weight management or otherwise.

Diet Paradigms for Overall Health

The Dietary Guidelines provide a basis for planning diets.7 The Food Guide Pyramid can be used to guide individuals in making healthy food choices to meet nutrient and calorie needs. The DRIs (Dietary Reference Intakes)8,9 were introduced in 1997 to build upon the earlier Recommended Dietary Allowances (RDA) as the standards for human nutrient requirements.10,11 The DRIs are being released in phases. Future DRIs will address nutrients that were not included in the past.

Dietary guidelines

The 2000 Dietary Guidelines were written by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (USDHHS) in order to provide guidance on making food choices that would promote health and prevent disease.7 The Food Guide Pyramid (described in the next section) can be used as an outline to meet these guidelines. Year 2000 USDHHS Dietary Guidelines7 are as follows:

* aim for a healthy weight;

* be physically active each day;

* let the Food Guide Pyramid guide your food choices;

* choose a variety of grains daily, especially whole grains;

* choose a variety of fruits and vegetables daily;

* keep food safe to eat;

* choose foods that are low in saturated fat and choles- terol, and moderate in total fat;

* choose beverages and foods to moderate your intake of sugars;

* choose and prepare foods with less salt; and

* if you drink alcoholic beverages, do so in moderation.

The USDA developed the Food Guide Pyramid in 1991 as a basic guide to selecting a healthful diet based on the Dietary Guidelines.12 Pyramids for the elderly and for children have been developed as well as pyramids for vegetarians and various ethnic cultures (http://www.nal.usda.gov/fnic/etext/000023.html). Each food group indicates a recommended number of servings needed to provide an adequate amount of daily nutrients. The range of portions varies to meet the varying energy and protein requirements of individuals.

IMAGE PHOTOGRAPH

The Food Guide Pyramid

Foods are grouped according to their overall nutrient content and are interchangeable for nutrient values within but NOT between groups. The grain group provides sources of simple and complex carbohydrates, trace elements, dietary fiber (in whole grain sources), and B vitamins. The fruit and vegetable groups provide dietary fiber and many nutrients consumers take in supplemental forms such as vitamin C, beta carotene and other carotenoids, vitaminA, fiber, and phytochemicals. Dairy products provide calcium and protein; fortified products are excellent sources of vitamins A and D. Calcium fortified soy 'dairy' products (soy cheeses and milk) also fall into this group. The protein group includes animal and vegetable sources. Vegetarian protein sources include nuts, beans, and tofu. Animal protein sources include meat, fish, poultry, game, and eggs. Animal protein products also provide vitamin B12. Fats, sweets, and oils, should be selected in limited amounts. This group includes margarine,butter, oil, cream cheese, and cream as well as ice cream, cakes, cookies, candy, and other snack foods and baked products high in fat and sugar. Unlike the other food groups, which list recommended number of servings, consumers are cautioned to minimize daily servings from this group.

Dietary reference intakes and recommended dietary allowances

Historically, the RDAs were used to guide nutrient recom- mendations for individuals varying with stage of life. The"RDAs are the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged (by the Food and Nutrition Board of the National Academy of Sciences) to be adequate to meet the known nutrient needs of practically all healthy persons."10(p1) The RDAs consisted of a single value for nutrient needs for various age groups. The DRIs provide essential and recommended levels for what was considered safe and adequate as well as upper limits of recommendations to avoid toxicity.

DRIs8,9 are recommended amounts of nutrients to reduce risk of chronic disease and prevent deficiencies.8,9 The DRIs provide guidelines for determining general nutrient needs of healthy individuals. Nutritional deficiencies may result from inadequate intake, decreased absorption or utilization, or increased metabolism or excretion. With increased consumer use of dietary supplements, the risks of nutrient toxicities have risen considerably.

DIETARY SUPPLEMENTS

According to the FDA Center for Food Safety and Applied Nutrition, dietary supplements are defined as products that supplement the diet and contain one or more dietary ingredients including vitamins,

minerals, amino acids, herbs, or botanicals.13 Supplements can be in the form of concentrates, metabolites, constituents, extracts, or a combination of forms that are "intended for ingestion as a capsule, powder, gelcap and not represented as a conventional food or as a sole item of a meal or the diet:13 There are 3 categories of dietary supplement ingredients--nutrient, botanical, and other. Nutrients include vitamins, minerals, trace elements, amino acids, carbohydrates, and fatty acids. Botanical supplements include herbs and are materials derived from plants and include fresh, dried, preserved, or extracted botanicals. The 'other' category includes non-nutrient supplements, phytochemicals, and items such as shark cartilage.

Labeling of Dietary Supplements

The 1994 Dietary Supplement Health and Education Act (DSHEA)14 established that dietary supplements do not need to follow the rigorous labeling standards applied to foods and drugs. Under DHSEA, dietary supplements can be sold without proving efficacy or safety. In 1999, the regulations were revised, requiring supplements to include a statement of 'identity' (name of content), quantity included, serving size, amount of active ingredient, and other ingredients listed in descending order by content as well as address of manufacturer. In 2000, "structure function" claims14 were introduced. Products must include manufacturer contact number for more information and the following statement "This product has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease" on the label. Structure/function claims allow the manufacturer to describe the supplement's effect on the 'structure' or 'function' of the human body. However, they can make claims about the effect of the product on the physiological function of the body such as "strengthening bones" or "supports the immune system."14

The responsibility for factual labeling and truth in content of the package or product falls on the consumer. The outcome is that the actual content of the ingredients in the supplements is not known unless supplements carry the United States Pharmacopoeia (USP) label. The USP (www.usp.org) establishes standards that assure the quality of dietary supplements. The USP label indicates the product is regulated to ensure it contains the amounts of the supplement stated on the product label. The USP is establishing voluntary standards for all dietary supplements. Supplements may qualify for the USP label if they are in compliance with the standards and if the product has a FDA approval or USP accepted use. USP labeling is increasingly being followed by the major vitamin/mineral manufacturers but remains less frequently used by the 'natural' supplement industry. The USP label is not required but assures the consumer that the dietary supplement meets requirements established by the USP.

Vitamin, Minerals, and Trace Elements

Required amounts of vitamins, minerals, and trace elements for health promotion and disease prevention are defined in the RDAs and updated DRIs. Orthomolecular nutrition, introduced by Linus Pauling in the 1960s, refers to the use of large doses of 'natural' substances such as vitamins, minerals, trace elements, and amino acids to treat and prevent disease. It is a popular form of CAM that can pose dangers. Water-soluble vitamins, the Bs and vitamin C are not typically stored in excess in our body;

excess amounts are excreted in urine. However, in some circumstances, competition for absorption (iron and zinc) can cause deficiencies of a nutrient; megadoses of one vitamin (folate) can mask the deficiency of another (vitamin B12). Scientific evidence of benefits of orthomolecular levels of nutrients has not been published. In addition to supplemental forms of vitamins, minerals and trace elements, one must account for food intake of these nutrients as well. Consumers must be wary of getting too much of a single nutrient. For example, an individual consuming recommended levels of dairy products and 1500 mg of calcium supplements per day may exceed the tolerable upper limit recommended for calcium.

The need for vitamin, mineral, and trace element supplements should be, first, based on diet adequacy followed by individual disease, lifestyle, or stage of life related factors that influence nutrient needs. Determining the need for supplements is probably best made by a registered dietitian, physician, or other primary care provider with the requisite education and training to make such recommendations. Pregnant women need supplemental doses of iron and folate; additional amounts of nutrients needed for pregnancy are found in an adequate diet. Smokers need additional vitamin C and possibly calcium, which also can be met with diet.

Nutrient supplements should not, and to some degree cannot, replace actual foods in the diet. For example, there are over 600 different carotenoids in nature; the potential benefits of these have not all been discovered. Simply taking vitamin A, beta-carotene and lycopene and vitamin C cannot replace the additional nutrients found in a tomato or the unique ways these nutrients are combined in the foods themselves. The beneficial effects of diets rich in fruits and vegetables may not be mimicked by diets rich in supplements of nutrients found in these foods. Consumers should be cautioned to consult an RD prior to making the decision to try orthomolecular nutrition. A multivitamin mineral supplement that provides up to 100% of the DRIs for nutrients and has the USP label is usually safe for healthy adults.

Herbs and Botanicals

Herbs are the most popular form of CAM today.15 They include all plant-derived materials, the fresh, dried, preserved, or extracted parts of plants. The broader term botanicals include trees such as the gingko tree. The challenge for herbal products lies in their plant nature and manufacturing standards. There are many variations in herb species, seasonal variations in concentration of herbs based on when they are harvested and variations in concentration depending on the form of herb used. Forms available include liquids, tinctures, extracts, creams, salves, ointments, teas, and concentrates. For example ginseng bark, extract, tincture, or tea can be purchased from the U.S., China, Korea, or Japan. The concentration of ginseng in the form or the origin may vary. The challenges are compounded by the lack of FDA regulations on manufacturing products.

The top selling herbs for 2000 were gingko biloba, ginseng, garlic, echinacea, St Johns Wort, saw palmetto, valerian, kava, and milk thistle.16 As a result of the lack of FDA standards for manufacturing and labeling of products, herbs may be sold with or without the 'active' ingredients of the product in the bottle and without information regarding actual timing of digestion, absorption or duration of effect, or

proper doses. Consistency of content between bottles/packages of the same product or other ingredients present in the package may vary.15 The lack of standardization of active ingredients makes knowledge of actual action of the herb difficult. The consumer may get differing amounts each time they take the product.

It is not the intent of this paper to address all herbal supplements. Current resources for such information are in Table 1. Two of the top 5 herbal supplements are garlic and echinacea. Garlic has been promoted to help lower cholesterol and improve immune function. Medicinal effects of garlic have only been reported with use of the supplement form or whole, unblemished, raw garlic. The cholesterol lowering effect of garlic is short term.17

Echinacea, a purple coneflower, has been heralded for its ability to prevent and shorten upper respiratory infections (URIs). Although it does have immunomodulatory effects; there is limited evidence of the role of echinacea in limiting severity of URIs after onset without preventive effects.18 There are 3 different species with multiple processing and application methods, factors that affect variability in product content and effect. A standardized defined preparation of echinacea is needed to conduct scientifically sound research.
IMAGE TABLE
Table 1.

Adverse effects of products have been reported15 in relation to drug-herb interactions as well as in innocent consumers taking what they think is a'natural' herb. Individu- als should stop taking all herbs up to 3 weeks before undergoing general anesthesia, particularly kava, valerian root, St. John's Wort, and gingko,19 which can lengthen the duration of the effect of the anesthesia. St. Johns Wort can negatively impact protease inhibitors used to treat HIV19 as well as other drugs metabolized by the same pathway. Similarly, individuals taking coumadin or other anticoagulants should avoid garlic, vitamin E, gingko, and other herbs that can potentiate a longer bleeding time. Individuals taking immunomodulatory medications or with immune related disorders should not use echinacea, an immunostimulant, without consulting a health provider well versed in herbal medicine. These examples support the need for health professionals to question patients regarding their use of supplements and educate them appropriately to promote health and prevent illness or any unnecessary complications.

In order for practitioners to feel comfortable in talking about dietary supplements with patients, it is important they have resources available. Consumer Laboratories is an independent laboratory that evaluates the quality and safety of dietary supplements (www.consumerlabs.com). Electronic resources are selected in place of print because they are more frequently updated.

Glucosamine

Of particular interest to physical therapists may be the dietary supplement glucosamine sulfate. Glucosamine is sometimes combined with chondroitin sulfate and marketed as an alternative therapy for osteoarthritis (OA) management. Glucosamine supplementation may control pain, reduce disease

progression, and is well-tolerated.20 Glucosamine appears to stimulate collagen production and reduce breakdown of healthy tissue, leading researchers to speculate that this compound relieves arthritis and reverses the degenerative process.21

Glucosamine studies22-24 show evidence of cartilage regeneration, but the research is mainly criticized because of short duration and small samples.23 A meta-analysis concluded that reported results of successful treatment with glucosamine and chondroitin might be exaggerated but that the supplements may in fact be effective.22 In 1999, NCCAM and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) awarded the first multi-center study for glucosamine and chondroitin in knee osteoarthritis. The 4-year $6.6 million study at the University of Utah includes 9 centers and over 1000 patients in a double blind placebo controlled study.24 Potential users of glucosamine should become educated about the positive and negative effects, consult with their physicians, and continue proven management techniques.25 Glucosamine has been shown to cause insulin resistance in a rat model,26 long-term efficacy and safety are unknown, and judicious evaluation should be sought. It is imperative that practitioners have an increased awareness of glucosamine, as people with arthritis will continue to seek alternative treatments.27

FUNCTIONAL FOODS, SOY PROTEIN, AND ISOFLAVONES

Functional foods represent one of the fastest growing food categories in the US diet.28-30 They are defined as having an identified value leading to health benefits as "foods that provide health benefits beyond basic nutrition,"29 typically ones in which the concentrations of one or more ingredients have been manipulated or modified to enhance their contribution to a healthful diet.29 Phytochemicals and soy protein are 2 functional foods that are increasingly popular because of their potential health promotion and disease prevention benefits.28

Phytochemicals

Phytochemicals (phytos comes from Greek meaning plant) are naturally occurring compounds in plant foods that may act similar to hormones or other substances in the human body. Phytoestrogens, a subclass of phytochemicals similar to endogenous estrogens, can fit into estrogen receptors and mimic the hormonal action. In addition to food sources, supplemental forms of these nutrients are also available.

Phytochemicals are found in, but not limited to, foods such as soy, other legumes, seeds, vegetables, some herbs such as black cohosh, and green tea, some of which may be instrumental in the prevention of diseases such as osteoporosis, cardiovascular diseases, and cancers.343 There are 2 main categories of foods containing phytoestrogens. Isoflavones, in particular genistein, daidzein, and glycetein, found in legumes such as kidney beans, black beans, chickpeas, and soybeans, have naturally occurring phytoestrogens. Lignins are phytoestrogen precursors that are digested and converted into active, potentially disease-preventing compounds. Foods rich in the lignin phytoestrogen precursors are seeds, particularly flaxseed, whole grains, bran, and vegetables such as carrots, broccoli, asparagus, and

squash.30

Soy Products

Soy products have a superior concentration of phytoestrogens. Actual content varies in quantity and quality within individual foods. Processed soy products such as soy burgers, some soy flour, and oil (vegetable oil is usually soy-- based) may not have available isoflavones because of losses in processing.32 Soymilk, soybeans, and soy products (tofu, tempeh, and texturized soy protein) offer the greatest concentrations of phytoestrogens. Supplements are now available but research regarding long-term use of high concentrations found in supplement form is not available; these should be used with skepticism.

Phytoestrogens may help reduce risk of osteoporosis, cardiovascular disease, some cancers, and alleviate symptoms of menopause.31-4 Animal research using phytoestrogens has demonstrated their role in preventing bone loss; they may also replace bone density.32 In population studies, high soy intake is associated with fewer menopausal symptoms.33

Soy protein can lower low-density lipoprotein (LDL) and raise high-density lipoprotein (HDL) cholesterol levels to improve the overall lipid profile.34 Antioxidant properties of phytochemicals may protect against LDL oxidation,35 isoflavones appear to favorably affect blood vessel function,36 genistein inhibits blood clot and growth of cells leading to artery blockage.37 Soy is low in saturated fat, cholesterol free, with a significant amount of omega-3 fatty acids and fiber (soy beans and tempeh) per serving, making it a healthy food choice for promoting cardiovascular wellness. The FDA authorized the use of health claims regarding the role of soy protein, independent of isoflavone content, in reducing the risk of coronary heart disease on food labels containing soy protein.38 The recommendation is to include 4 servings of at least 6.25 grams of soy protein per day for a total of at least 25 grams of soy protein each day for cardiovascular risk reduction.

Phytoestrogens may be referred to as a natural form of hormone replacement therapy. The basis for this claim stems from observations of Asian populations consuming high intakes of soy and isoflavones, and from the knowledge of the action of the phytochemical's estrogen-like activity on the receptor sites for depleted estrogen.39 The isoflavone, genistein, inhibits enzyme activity that controls cancer cell growth,40 acts as an antioxidant,40 and may be responsible for metabolic "signaling" to suppress mammary cancer but need to ingest the isoflavone begins at a young age.43 Genistein acts as a weak estrogen and may not be appropriate in individuals with a history of hormonesensitive cancers.

INTEGRATION INTO PATIENT/CLIENT CARE

Basic screening, assessment, education, and referral to appropriate providers is within the scope of practice of all health professionals.44 The rubric of comprehensive patient care includes basic diet/nutrition screening, questions regarding use of special diets or dietary supplements, and basic education and referral to an RD for more comprehensive nutrition care, typically referred to as medical

nutrition therapy The PT can screen patients for nutrition risk, provide basic education regarding diet and supplements and refer patients to an RD. The values of this component of patient care are multifaceted. It provides the PT with a knowledge of potential diet or nutrition inadequacies which may interfere patient response to treatment; knowledge of use of supplements may help prevent drug-supplement interactions and finally it gives the PT a more comprehensive picture of the patient's overall health.

Patient histories should include basic questions regarding intake of foods from all of the food groups, use of dietary supplements and functional foods as well as CAM therapies. A simple and efficient approach is to ask the patient "Tell me everything you had to eat and drink on a typical day from when you get up until you go to bed." The PT can then categorize the foods by their respective food groups and determine overall diet adequacy based on a comparison of the individual's intake to the food guide pyramid. Nonjudgmental questioning may be phrased as "In order to get as complete a picture as possible of all sources of health aids, we would like to ask about your use of other forms of health care, frequently this is called complementary or alternative medicine."46 Patient reasons for use, belief systems, and actual preparations used should be questioned.47 Health professionals need to ask the 'hows' (how long, how much, how often), the 'whats' (what form,what brand,what dose,what else), the 'whys' (why do you take it, why was it recommended) and the outcomes. Armed with that information, the PT can then go look up supplements the resources listed in Table 1. Following a careful review of the risks, benefits,actions and potential interactions of any supplements in conjunction with the patient's drug(s), it is important that the PT share that information with the patient.

In approaching patients we should remain "humble about our mix of art and science"47 in health care. Health professionals need to learn about CAM to facilitate open discussions with patients and explore the realm of therapies used. Physical therapists should review issues of product safety and efficacy and encourage use of standardized products selected with care with patients. Secondly, patient expectations should be discussed and followed up on along with other side effects experienced. It is very important that we help patients understand that many supplements can act like and interfere with drugs. Drugs have benefits and risks, can interact with other drugs, and should be taken one at a time in recommended doses. Adding several new supplements at one time does not allow an evaluation of individual product benefits or side effects.

A clear understanding of the fundamental principles of a healthful diet and careful and cautious use of dietary supplements will assist the PT in the provision of comprehensive patient care. Diet and nutrition can promote 'healing' as well as 'prevent' disease; they are the cornerstones of health promotion and disease prevention.

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