Using Dietary Supplements in Practice: What You Need to Know

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According to the Academy of Nutrition and Dietetics’ (Academy) position paper on Nutrient Supplementation, “dietetics practitioners should position themselves as the first source of information on nutrient supplementation.” In order to accomplish this, Registered Dietitian Nutritionists (RDNs) must keep up to date on issues associated with the regulation, safety and efficacy of dietary supplements (DS). Over half of the American public is taking some form of DS, and many of them may not be well informed. Functional medicine dietitians often use DS as part of the Nutrition Care Process, therefore it is important that they be well aware of the resources available for keeping DS knowledge current.

Defining Dietary Supplements

According to the Food and Drug Administration (FDA), a dietary supplement is defined as a product that:

1. Is intended to be a supplement to the diet
2. Is intended to be taken by mouth—this excludes other routes of administration, such as intra-nasal, transdermal, and suppository
3. Contains one or more dietary ingredients, including:
   - Macronutrients (protein, carbohydrates, fats)
   - Vitamins and minerals
   - Herbs and botanicals
   - “Other” dietary substances that are either grandfathered in or are approved as New Dietary Ingredients (NDIs), such as

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Objectives

After reading this CPE article, the nutrition professional will be able to:
1. Describe how dietary supplements are regulated.
2. Discuss the rationale for recommending dietary supplements.
3. Name at least 4 trustworthy resources for obtaining information about dietary supplements.
4. Identify at least 5 questions to ask when evaluating a supplement manufacturer.
5. Discuss the various factors to consider when recommending multivitamin, omega-3 fatty acid, and probiotic supplements.
THE INTEGRATIVE RD

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Editor’s Corner

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Fall is upon us and that means it is time for FNCE®. As noted by our Chair, Betsy Redmond, PhD, MMSc, RD, LD, the Executive Committee has been busy planning events for not only 2013, but for 2014 and years to come.

This time of year is always anticipated with the local Farmer’s Markets offering fruits of their harvest, while those of us fortunate enough to have a garden are trying to find a home for all those zucchinis and tomatoes! The markets remind me of how important a variety of produce in our diet is and produce’s contribution to integrative and functional nutrition with their bright colors, fiber and more. Once this season of harvest closes and the variety and quality of produce is less than optimal, we and our clients often turn to dietary supplements to supplement the diet. The CPE article in this issue will help you sort the ‘wheat from the chaff’ by providing specific information about how to choose the safest and most effective dietary supplements for you and your clients.

Speaking of produce…a review of the conference Justice Begins With Seeds on genetically modified organisms provides a brief view of the controversial topic on genetic engineering of seeds and food products that many of us are asked about. Stay tuned for more information about this topic from DIFM and our sister DPG–Hunger and Environmental Nutrition. This review is complimented by a book review of Making Peace with the Earth.

I cannot conclude my column without mentioning the devastating floods in eastern Colorado that have impacted many of our members. Our thoughts are with them at this difficult time and those unable to attend and network with us at FNCE®.

See you in Houston!

Sarah

Those of you who would like to contribute an article or have topics that you would like to see in future issues, please feel free to drop me an email or give me a call—peaknut70@gmail.com or 970-216-2356—or contact any one of the capable DIFM leaders listed in this newsletter.
It's been busy for the DIFM Executive Committee (EC). The EC has been working hard, and we are excited about the DIFM educational and social offerings at FNCE 2013, http://integrativerd.org/events/. As I write this, we are already preparing for FNCE 2014. The interest in integrative and functional nutrition is high, and DIFM members are in the best position to provide evidence-based and practice-proven services to clients and the public, and to educate members of the Academy, nutritionists, and other interested clinicians.

It is important to know that there are many who are unfamiliar with integrative and functional nutrition and wonder if it is real. Is there any evidence for it and is it better than traditional nutrition protocols or treatments? It's a fair question. It is imperative that functional RDNs know the science behind the products and services we use, and the claims we make. As a practitioner, I usually stress two aspects of integrative and functional nutrition: first, you don't have to use integrative and functional nutrition instead of conventional treatments, you can use it along with traditional therapies, and second, yes, there is evidence for it as a substantiated practice. As an example, conventional thinking sees frank vitamin and mineral deficiencies as rare, while integrative and functional nutritionists understand that nutrient insufficiencies are more common and can lead to functional impairments of biochemical pathways, which may lead to or exacerbate current health issues.

It is important that we use our strong science backgrounds and remain objective when evaluating evidence. Companies often make claims to distinguish themselves, and may exaggerate the truth. There are also long held beliefs or assumptions of truth within the integrative and functional community that may or may not have good science behind them. There are several ways to seek out the truth. First, find out what is known in the current scientific literature in PubMed or Medscape. Are there independent research organizations or universities agreeing with what they claim? For nutritional testing I go to the Institute of Medicine (IOM) site. In setting the DRIs, they review all the ways a nutrient has been tested, and give a review. For products, such as supplements, I perform my literature search and then look at the Natural Medicines Comprehensive Database to review how much science there is. The membership to the Natural Medicines Comprehensive Database comes free with your DIFM membership and may be accessed on the DIFM website, www.IntegrativeRD.org.

As integrative and functional nutrition providers, we believe in making sure that the non-conventional treatments we integrate have good biological function. To learn more about what we have to offer and what we are all about, visit us online at www.IntegrativeRD.org, or, if you are at FNCE in Houston, stop by and visit us at the Product Market Place and the DPG Showcase.

With a coordinated voice we can all move this knowledge forward.

Betsy

Dr. Elizabeth Redmond, PhD, MMSc, RD, LD is currently Chair of DIFM. She received her master’s from Emory University, and doctorate in nutrition from the University of Georgia. She is co-author of several publications including the Standards of Practice (SOP) for Dietitians in Integrative and Functional Medicine, and the Laboratory Evaluations for Integrative and Functional Medicine (2008) textbook. Contact Dr. Redmond at 3425 Corporate Way, Duluth, GA 30096 or email eredmond@gdx.net.
Some hormones, including:
- Thyroid hormone, cortisol, estrogen, progesterone, or testosterone
- Pathogenic bacteria
- Human tissue

**Regulation of Dietary Supplements**

Two government agencies are responsible for the regulation of dietary supplements. The FDA oversees safety concerns, and the Federal Trade Commission (FTC) oversees advertising, health and label claims.

Prior to the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, DS were manufactured, marketed and sold without specific regulation. By the early 1990s, the number of Americans consuming DS had reached a critical mass, and lawmakers were ready to take action to impose regulation. By then, consumers had become accustomed to open access to a wide variety of supplements and launched massive grassroots campaigns that, along with lobbying from the DS industry, greatly influenced the regulatory process.

In the end, the law was written in a way that preserved consumer access to DS, but still provided a framework for safety. According to DSHEA, all DS on the market prior to 1994 are considered generally recognized as safe (GRAS). It defines DS as a sub-category of food, the current regulations are only concerned with safety, not efficacy.

Under DSHEA, it is up to consumers to educate themselves about the DS they are taking, so the FDA instituted the Office of Dietary Supplements (ODS) to fund DS research and disseminate credible information about DS to consumers.

Additional DS regulations set forth by DSHEA:
- **Supplement Facts Panel** that defines how ingredients must be listed on the label.
- **Structure Function claims vs. Health claims.** Supplement companies are not allowed to list disease states or make specific health claims on a DS label. A structure/function claim allows for the listing of a structure or function of the body or a lifecycle stage. For example, “supports cardiovascular health” is permissible while “reduces blood pressure” is not.
- **Dissemination of product literature.** DS companies and retailers are not permitted to display product information or technical data sheets next to products, as they can mislead consumers.
- **Good Manufacturing Practices (GMPs):** Although the mandate for GMPs was made at the time DSHEA was enacted, it took until 2007 for a final draft to be accepted and 2010 for full implementation across all DS manufacturers. According to the regulation, manufacturers of DS must meet minimum standards for production and are subject to random audits.

The DS GMPs regulate:
- The design and construction of physical plants
- Maintenance & cleaning procedures
- Proper manufacturing operations
- Quality control procedures
- Testing incoming and in-process materials and final products
- Handling consumer complaints
- Maintaining records.

The FDA has a fairly robust auditing program and inspects more than 300 DS manufacturers per year. According to Daniel Fabricant, PhD, Director of Dietary Supplement Programs at the FDA, almost 70% of companies audited so far are in non-compliance with the GMPs. Of the audits done in 2012 (N=341), 27% of companies were in compliance, 35% were in partial non-compliance, 34% were in major non-compliance, and 91 warning letters were sent. The most common non-compliance issues were failure to test products appropriately, failure to keep adequate records of testing, and presence of adulterants such as contaminants, non-approved dietary ingredients and pharmaceutical drugs. In the near future, Fabricant estimates many of the non-compliant companies will be shut down by the FDA, which will ultimately help ensure safety in the DS industry.

**Industry Self-Regulation**

Founded in 1936, Natural Products Association (NPA) is the largest non-profit organization to advocate for the rights of consumers to have access to and for retailers to sell DS. Prior to implementation of GMPs, the NPA was a leader in launching a certification program to ensure its members were producing high quality supplements. In 1999, they were the first organization to publish GMPs and provide third party certification. The NPA still offers this certification today and has revised its GMPs to mirror the FDA’s, except where its standards exceed those of the FDA. The NPA offers member companies training on how to be compliant with GMPs, a service the federal government does not offer.

**Third Party Certification**

By law, all DS manufacturers must be in compliance with the GMPs. The FDA does random audits of companies to ensure compliance, but companies do not have to submit proof of compliance unless they are audited. Some DS companies choose to be third party certified in
order to engender greater consumer confidence in their products. Companies such as US Pharmacopeia (USP), NSF International and the NPA provide this service for a fee to DS companies in exchange for a certification stamp on product labels.7-9

In order to sell DS internationally, some companies undergo additional certification from agencies such as the Australian Therapeutic Goods Administration (TGA). NSF International also offers an NSF Certified for Sport® Program so that athletes can be sure their DS do not contain banned substances.10,11

Industry Watchdogs
Several companies provide unsolicited post-market surveillance of DS products to ensure quality and integrity in the industry. Two of the most prominent are Consumer Labs and the Center for Science in the Public Interest.12,13 Consumer Labs pulls products off of store shelves and tests them to verify that they meet label claims and are free from contaminants. Results are published on a subscription-based website, but some information is available for free. Center for Science in the Public Interest is a non-profit organization in Washington, DC that surveys health claims made about DS and reports false and misleading claims to the Federal Trade Commission (FTC).

Safety Issues
Under DSHEA, DS manufacturers are solely responsible for ensuring that their products are safe. There is no product registration, no approval of claims and no formula standards. The FDA does pre-market review of new dietary ingredients (NDI); to date only 760 have been submitted, of which 460 have been denied.3 Even if an NDI is reviewed by the FDA, that is no guarantee of safety. There are over 85,000 products on the market with many NDIs that have not been submitted or approved.3 If a dietary supplement causes harm, it is up to the FDA to prove the supplement is unsafe and remove it from the market.

Regulation of the DS industry is a daunting task for the government under the current legislation. Between 2008 and 2011, the FDA received 6,307 adverse event reports related to DS. Of those, 71% were serious adverse events. Interesting to note, 2.7 million adverse drug events were reported during that same time period, of which 63% were considered serious.14 Furthermore, from 2008 through 2010, poison centers across the country received 1,000 more adverse event reports related to DS than the FDA. It is estimated that many adverse events are not being reported or are not being reported correctly. Common barriers to reporting include consumers downplaying the significance of their reaction, not knowing where or how to report, and embarrassment.15

The DS most commonly linked to health and safety concerns include those used for weight loss, performance enhancement (ergogenic aids), and sexual dysfunction.3,16,17 These supplements have the highest risk for contamination and adulteration with unapproved ingredients and drugs, especially when purchased from obscure and/or online retailers. Internet sales of DS is the fastest growing retail market and also the hardest to regulate.3 Because ergogenic supplements are so popular on military bases, the Department of Defense has created an excellent website to evaluate the safety of these products called Operation Supplement Safety (http://hprc-online.org/dietary-supplements/opss).18

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act was passed. It mandates that manufacturers and distributors of DS must include contact information on their packaging and report serious adverse events (SAE) to the FDA via the Medwatch Program.19 SAE’s are defined as death, a life threatening event, incapacitation, hospitalization, or a birth defect. Healthcare providers and consumers are not mandatory reporters under the law but are strongly encouraged to report adverse events. They can sign up for email alerts at the FDA website.16

To date, very few DS have been banned by the FDA. Those banned include Ephedra sinica, aristolochic acid, and most recently dimethylamylamine (DMAA). In many cases of suspected harm, causality is difficult to prove. Herbal products may pose a significant risk in some cases as they have multiple chemical constituents, many of which have not been adequately characterized.20 Bill Gurley, PhD from the from University of Arkansas, College of Pharmacy has written two excellent articles on the pharmacokinetics and safety of herbal supplements.21,22 Hypericum perforatum (St. John’s Wort) is by far the most problematic common herb, as it can increase metabolism of many drug classes including HIV and anti-rejection medications and oral contraceptives. Hydrastis canadensis (Goldenseal), Schisandra chinensis and black pepper extract can all cause a similar reaction.22 Gurley stresses that most popular herbs are very safe and do not cause significant drug-nutrient interactions (DNI). The safest way to use herbs is in food and culinary preparation. When herbs are made into extracts and tinctures, the risk for DNI and adverse events may increase because active constituents are concentrated and the therapeutic effect is magnified. It is important for any RDN who recommends herbal products therapeutically to seek additional herbal training.

To ensure safety, it is important to use an evidence-based approach when recommending DS and to screen for drug-nutrient interactions and over-supplementation. DS that come from quality companies and are used appropriately appear to be safe.

Rationale for Recommending Dietary Supplements
Before recommending supplements, the RDN must determine the clinical indications for their use. The following factors should be considered:

• Does the patient have a nutrient
deficiency as evidenced by results of nutrient analysis questionnaires or software programs, clinical signs and symptoms, or laboratory tests?

• Does the patient have an increased need for nutrients as a result of inborn errors of metabolism such as absorption defects, transport defects, abnormal enzyme production, or excessive renal losses?

• Does the patient have elevated needs secondary to acute or chronic illness? Nutrient requirements are higher in disease states that result in an increased metabolic rate, such as hyperthyroidism.23-25 Likewise, nutrient needs are often increased in people with gastrointestinal disorders where malabsorption occurs, such as small-bowel bacterial overgrowth, hypochlorhydria, inflammatory bowel disease, and pancreatic enzyme deficiency.26-29

• Might there be drug-induced nutrient depletions? Common examples include vitamin B₁₂, coenzyme Q₁₀, and calcium deficiencies related to the use of antacids, statins, and corticosteroids, respectively.

• Are there increased nutrient needs related to genetic factors? For example, about 5–15% of North Americans and Europeans are homozygous for the polymorphism of the 5,10-methylenetetrahydrofolate reductase (MTHFR) gene.30 These individuals have a tendency to develop hyperhomocysteinemia (a risk factor for many health conditions, including heart disease), which can usually be corrected by a moderate increase in folate intake. Because increased needs are difficult to meet with dietary folate intake alone, supplementation is often recommended.30

• Might the patient benefit from nutrient supplementation to support a physiologic function? A number of different nutrients have been found to have pharmacological or physiological effects when given at concentrations greater than those needed to prevent deficiency. For example, since magnesium increases the solubility of calcium oxalate, increasing the urinary excretion of magnesium by oral supplementation has value in decreasing the incidence of calcium oxalate kidney stones.31

It is important to remember that the Recommended Dietary Allowances (RDAs) and Adequate Intakes (AIs) establish nutrient intake levels for healthy people and may not address the specific needs of every individual. Those who are very active/athletic, or who have chronic sleep issues, chronic fatigue, a strong family history of a disease condition, or non-diagnostic lab abnormalities may benefit from dietary supplementation.32 The RDN should also bear in mind that even those who seemingly have a dietary intake that meets RDAs/AIs may require additional nutrient support if their food choices are primarily from highly processed or otherwise inferior sources and/or when cooking techniques or other issues lessen the nutrient quality of their diet, particularly if they are not willing or able to change these factors to affect improvements.

Because of the low risk of adverse effects and the relatively low cost of most DS, the RDN should be aware of all potentially useful clinical applications, not just those that are supported by the highest levels of evidence. While there is much more evidence available than is commonly thought, the fact that many DS are not patentable remains a hurdle to further research. Companies who seek high profit potential in their product offerings are not likely to invest in costly studies of dietary supplements. In addition, the RDN should not hesitate to view older research as valid. Vitamin C, for example, has not changed over the years. There is no reason to believe good research conducted in the 1960s would be any less valid than research done today.

Resources to Help Determine Your Patients’ Dietary Supplement Needs

Whenever possible, validate the need for supplementation with laboratory testing. Specific nutrient levels like vitamin B₁₂, vitamin D, and zinc can be obtained through standard laboratories that offer traditional lab testing. Specialty functional medicine testing, such as organic acid tests, micronutrient analysis, comprehensive digestive stool analysis, fatty acid profiles, and nutrigenomic testing can be of great use. Further training in functional nutrition can better position the RDN to assess and utilize these tests.

The RDN should always assess potential drug-nutrient interactions. Many drugs will influence nutritional status, and this should be taken into consideration when making recommendations for DS. Likewise, certain foods, nutrients, and herbs could interfere with a medication’s effectiveness. Evidence-based recommendations and detailed information on many DS can be accessed online at the following websites:

Free Sites:

• Office of Dietary Supplements (ODS): http://ods.od.nih.gov/. The search box will filter searches in PUBMED to DS research.

• National Center for Complementary and Alternative Medicine (NCCAM): http://nccam.nih.gov/. This site is not specific to DS but includes all forms of complementary and alternative medicine.

• Linus Pauling Institute Micronutrient Information Center: http://lpi.oregonstate.edu/infocenter/

• Vitamin Herb University: www.vitaminherbuiversity.com

• Integrative Therapeutics Drug Nutrient Interactions Checker: www.integrativepro.com/Resources/Professional-Resources/Drug-Nutrient-Interaction-Checker

• Drug Interactions Checker: www.drugs.com/drug_interactions.html/

• Medscape Drug Interaction Checker: http://reference.medscape.com/drug-
interactions that cause digestive or absorptive capacity. Some examples of chelates are glycinate, citrate, aspartate, and taurate.

• **Active B vitamins.** Many functional medicine practitioners consider the active form of a B vitamin superior to the inactive version. This is especially true for patients who have been identified as having genetic polymorphisms, which may compromise their ability to metabolize certain nutrients. Active B vitamins include pyridoxyl 5-phosphate (vitamin B₆, usually given as inactive pyridoxine hydrochloride), methylcobalamin (vitamin B₁₂, usually given as inactive cyanocobalamin) and methylenetetrahydrofolate (folic acid).

• **Natural Vitamin E.** While food-based products are popular due in part to the notion that “natural” is better utilized than synthetic, there is little evidence to support this theory. However, as Dr. Alan Gaby describes in *Nutritional Medicine*, with vitamin E, there is a distinct difference in utilization. Seven of the eight isomers in synthetic vitamin E are not normally present in the human body, and it is possible that some of these isomers may have subtle adverse effects. For that reason, natural vitamin E (D-alpha tocopherol) may be preferable to its synthetic counterpart (DL-alpha tocopherol). In the human body, only the D form is recognized. Although the L form may have antioxidant activity, it may actually inhibit the D form from entering cell membranes. Additionally, a higher quality vitamin E product will have not just D-alpha tocopherol, but will offer mixed tocopherols, as these are thought to mirror the vitamin E found in food and provide greater benefit. Mixed tocopherols are more expensive to produce than alpha-tocopherol, and some products labeled as vitamin E with mixed tocopherols contain only token amounts of the latter. Reputable mixed tocopherol products should specify the amount of gamma-tocopherol present.

Avoid inferior ingredients

Just as the functional RDN might encourage patients to choose a “clean” diet of whole and minimally-processed foods, he or she should also recommend DS with minimal processing and excipients (inactive substances) such as preservatives, artificial colorings, flavorings and sweeteners, excess fillers/binders and sugar or high fructose corn syrup. Many practitioners also like to choose products that are free of genetically modified ingredients. For patients with food allergies or sensitivities, ensuring that DS are free from potentially problematic ingredients is vital. It is up to the practitioner to determine which companies both manufacture at the highest quality and use the highest quality ingredients. A formal audit form may be helpful, such as The IMCJ (Integrative Clinician's Medical Journal) Supplement Quality Audit Form. When choosing a supplement manufacturer, some questions a healthcare provider may wish to ask include:

• Does the facility comply with DS or pharmaceutical GMPs?
• Has the company been audited to assure compliance with GMPs? How often? By whom?
• Does the manufacturer have an in-house laboratory? What type?
• Are identity tests performed on each lot of raw materials?
• Are raw materials tested for heavy metal, pesticide, and microbiological contaminants?
• Are in-process and finished products protected against contamination with extraneous materials?
• What, if any, agents are used for extraction? Are finished products tested for these agents?
• Is each lot of finished product tested for identity and for contamination by heavy metals, pesticides and microbes?
• Is each lot of finished product evaluated for bioavailability through dissolution testing?
• Is each container of finished product identified with a lot number to allow the
product to be traced?

• Are herbs used sustainably harvested? Are they verified for the correct genus and species?

• What, if any, additives, diluents, preservatives or fillers are used in the company’s products?

• Are Certificates of Analysis available for all raw materials used? A Certificate of Analysis provides detailed information about the identity, quality and purity of the raw material.

• Are written procedures available as to how Certificates of Analysis are validated?

• Who formulates their products? What formal training do they have?

• Do they rely on published clinical studies in formulating their products?

• Are any of their products used in published research?

The answers to such questions can be very helpful as RDNs choose which supplements to recommend and/or carry in their private practice dispensaries. Professional lines that distribute DS through licensed healthcare providers are generally considered higher quality, as they often go beyond standard GMP requirements. A good company’s website usually provides much information to back-up their quality claims.

**The Most Popular Dietary Supplements**

As a foundation, the RDN should have good knowledge of the most commonly recommended DS. These include multivitamin/mineral (MVI), probiotic and fish oil/omega-3 fatty acid supplements. Once the RDN has determined the clinical indication and ruled out any contraindications for use, there are many questions to consider when deciding which supplement to recommend for a particular patient or client.

**Multivitamin/mineral (MVI).** When choosing an MVI, does the patient need iron, or would an iron-free formula be more appropriate? Does the supplement contain natural or synthetic vitamin E? Are the B vitamins in their active or inactive form, and how important is this for the client? Does the formulation include minerals, and if so, are they chelated? Would a gender and/or age-specific formula best meet the patient’s needs?

Another factor to weigh is the dosing: one-a-day type formulas may engender better compliance than multi-dose MVIs, but they often provide nutrients at the RDA level, while the latter generally has greater potency. When higher levels of nutrients are warranted—or when digestion or absorption is compromised—MVIs may be best taken in divided doses throughout the day for optimal absorption, as one high dose is likely to exceed the body’s absorptive capacity. For example, plasma pyridoxal-5-phosphate levels have been shown to increase as oral doses of pyridoxine are increased from 10 to 25 mg and from 25 to 50 mg, but not when the dose is increased from 50 to 100 mg.40

Specialty MVI formulations that claim to support cardiovascular health, immune function or vision, or formulas that come loaded with extras, such as probiotics, essential fatty acids (EFA), enzymes, or herbs may be alluring, but one should bear in mind that the additional ingredients may not be present in levels high enough to be therapeutic. Additionally, the more ingredients there are, the greater the potential for allergic reactions in highly sensitive patients.

**Probiotics.** Recent scientific research has contributed to the great increase in interest in probiotic supplements in the last several years. When recommending probiotics, the RDN should consider which specific strains of probiotics have been shown effective for which specific conditions and try to recommend a product that most closely matches. For example, a patient might benefit from the use or addition of Saccharomyces boulardii, a yeast that has been shown to help regulate the microbial balance of the gut and has demonstrated effectiveness in the treatment of inflammatory gastrointestinal diseases.41 In the absence of a specific indication, recommending a multi-strain product is probably best.42

Probiotics come in many forms, including powders, capsules, freeze-dried, enteric-coated, and pearlized. Some forms, such as pearlized, are more stable and ensure a high number of viable organisms are delivered. Refrigeration is recommended for many probiotics to maintain viability, especially for powdered forms more vulnerable to degradation. That said, a refrigerated product does not automatically denote the highest quality product. Furthermore, a product that has to be refrigerated may present a hindrance to compliance if the patient is likely to forget about something hiding in the fridge instead of out with all the rest of his or her supplements.

From 500 million to 450 billion, probiotic supplements vary widely in the number of colony forming units (CFU) they contain. The RDN should check the research to determine if there is a recommended strength or dose for the particular indication for which he or she are recommending probiotics. Another way to determine specific requirements is to refer to results of a comprehensive digestive stool analysis test, which would indicate any deficiency in specific strains. Recommended dosing for general health maintenance is 1-10 billion CFU of a combination of at least the two main strains, lactobacillus and bifidus.

**Fish Oil/Omega-3 Fatty Acids.** The purity and stability of omega-3 fatty acids are two of the most important aspects to consider when choosing this class of supplement. To evaluate purity, ask the manufacturer for a certificate of analysis from a third-party independent assay. Consider if each batch was assayed or only a sample batch. For a report comparing different brands of omega-3 DS for mercury, polychlorinated biphenyls, and other contaminants, consult Consumer Lab. A product’s stability is measured by its Totox value, which indicates the total oxidation of a sample.43 If a company cannot provide this information, the product may not be the ideal choice. It is important to keep in mind that the more an oil is manipulated (e.g. concentrated), the less stable it...
may be. Stability is an important consideration when choosing fish oil, as rancid oil may be worse than no oil at all.

Other factors to consider when choosing omega-3 supplements:

- **The source:** Flax or fish. While evidence suggests that flax is less effective in reducing inflammation in certain individuals, it is a viable alternative to fish oil for those with allergies, restrictions, or intolerance.

- **The form:** Omega-3 supplements can be made from ethyl esters (EE) or triglycerides (TG). Unrefined fish oil contains TGs in varied amounts and is thought to be superior to EEs in absorption and bioavailability.

- **Maintaining balance:** While supplementation of omega-3s is often indicated due to dietary insufficiency, long term or high dose supplementation may tip the scales toward excess. The proper balance of omega-6 to omega-3 fatty acids (usually 4:1) is crucial to optimal health. In some cases, omega-6 supplements, such as gamma-linolenic acid from evening primrose or borage seed oil, may also be indicated. Red blood cell (RBC) fatty acid testing is highly recommended for determining a patient's fatty acid needs.

**Other popular DS.** Calcium, magnesium, digestive enzymes, protein powders, detoxification support formulas, and individual vitamins like D, B₁₂ and folic acid are among the many other popular DS that RDNs trained in functional nutrition recommend. While it is beyond the scope of the present article to detail each of these here, the previous examples should give the RDN an appreciation for all there is to consider when choosing the appropriate supplement for any particular indication. It is highly recommended that the RDN obtain additional training on DS to ensure he or she makes appropriate recommendations.

**Form, Dosage, and Other Factors**

**Form.** Dietary supplements can come in many forms. When choosing, take into account the patient's absorptive capacity. Capsules are generally better absorbed than tablets; powders and liquids are considered easiest to absorb. Patient preference is also an important consideration. Some have difficulty swallowing tablets and prefer capsules, chewables, powders or liquids instead. Some like the convenience of a powder or liquid that can be added to food or beverages. Some are bothered by taste issues and prefer pills.

**Dosage.** Dosing guidelines can be obtained from many sources. Dosing is best when personalized to each patient whenever possible. Label recommendations are typically set for a 150-pound adult. Those who are considerably over or under this reference weight should have the dosing adjusted up or down as the case dictates. Products for children are often labeled for two different age ranges. The optimal dose of a particular substance however, can vary with the condition being treated, the preparation being used, and the patient's age and body weight. Dosing for children is usually lower, roughly in proportion to body weight, but with the consideration that nutrient requirements are increased during periods of growth. It is prudent to consult with the child's pediatrician when making supplement recommendations.

A patient's specific lab results can help determine dosage. For example, a vitamin level that comes up frankly deficient on lab results would require higher dosing than what is needed for someone whose level is sub-optimal but not yet deficient. Often times this is subjective and left up to the practitioner to decide. It may be prudent, especially for the less experienced practitioner, to start with a lesser dose and then increase based on the patient's clinical response. Sensitive patients or those with multiple allergies may require lower dosing for tolerance reasons.

**Tolerable Upper Intake Levels (ULs) are listed for some nutrients. UL is defined as “the highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.”**

In clinical practice, there are many instances, though, in which the potential benefits of dosages above the UL appear to outweigh the risks. For example, research shows that intravenous vitamin C at high doses, used in conjunction with chemotherapy or radiation, kills cancer cells in the early stages of cancer. Likewise, high doses of vitamin D are routinely prescribed for vitamin D deficiency, and niacin in high doses is indicated for hypertriglyceridemia.

The practitioner considering high doses of nutrients should be adequately trained in functional nutrition, and it is recommended the RDN work closely with a patient's other healthcare providers when considering higher or therapeutic doses of nutrients. Likewise, the RDN should be thorough in assessing all sources of nutrients from DS and foods to be sure the patient is not unintentionally getting excess. The RDN should impress upon patients the importance of providing a complete list of the DS they already take and to update the list with any they may add in the future. Monitor compliance to protocol recommendations. Some patients have a mindset that if a little is good, more is better. The RDN must be diligent about communicating dosing directions, the rationale for the given recommendations, and the risks of under or over-dosing.

**Other factors.** The best time of day to administer DS, whether they should be taken with meals or on an empty stomach, and how they interact with medications or other substances are also important to know. For example, fat-soluble vitamins are best given with food, whereas probiotics are often recommended away from food. An herb that supports sleep is obviously best given before bed. Likewise, many adrenal support supplements are best given first thing in the morning since they support alertness and energy levels. It is also important to pay attention to what should not be given at certain times due to potential interactions with prescription medications. For example, calcium and iron-containing supplements should be taken three to four hours before or after...
the thyroid medication, levothyroxine, as they can interfere with its absorption. Book and web resources can help guide you on what to give, how much to give, and when to give it.

Monitor Progress and Outcomes
The RDN should be aware of potential adverse effects and should monitor patients appropriately. While the use of DS usually has an excellent safety profile, side effects can occur, and high doses of some nutrients, such as vitamin A, vitamin B₃, vitamin B₆, vitamin D, zinc, iodine and selenium have occasionally caused serious toxic effects. More sensitive individuals could have allergic reactions. A higher risk of sensitivity reactions might occur in DS with more ingredients, especially from excipients, additives and colorings, but also from food-based ingredients and products containing herbs.

Patients with advanced renal insufficiency or hepatic insufficiency may develop toxicity from some nutrients, even when given at low doses. In those patients, DS may be contraindicated and should be undertaken only by practitioners fully trained in the management of these serious conditions.

Where to Get Additional Training
There clearly is a need for good quality education and training on the subject of DS, not to mention all aspects of the specialty of Functional Nutrition. The responsible practitioner will obtain this education before he or she dives into more than just the basics with his or her patients. What you don’t know can hurt your patients. Fortunately, there are many opportunities for education. The DIFM website is an excellent resource for degree programs and training specific to Functional Nutrition: www.integrativerd.org/resources/degrees-and-training/.

Conclusion
Dietary supplements can be an important part of the Nutrition Care Plan, especially for the patient of the functional medicine RDN. Many health conditions can be improved by making dietary changes, so it is important for practitioners to focus on food-based recommendations first. Scope of practice around the recommendation and sale of DS varies from state to state. The Academy has developed a useful interactive tool to help individuals define their scope of practice, which can be found at https://www.eatrigh.org/shop/product.

To provide members with more content in the newsletter, the CPEU questions and instructions for submission can be found in the full electronic version of the newsletter. Access the questions and certificate by going to the DIFM website, http://www.integrativerd.org/, log-in, and click on Archived Newsletters. There you will find the full electronic version of the newsletter, including the CPE article, followed directly by the Instructions for Completing the CPE Activity for Credit, the questions, and the CPE certificate that you may print off once you have completed the questions and submitted them for approval.

FREE CEUs

Esther Trepal, RD, MS, CDN is a registered dietitian at God’s Love We Deliver. For the past ten years, she has been educating people with HIV, cancer, diabetes and other chronic conditions on how to use food and nutrition to improve their health. She is also on the board of directors for Cook for Your Life. Esther holds a Master’s Degree in Nutrition from Columbia University in New York City. Contact Esther at etrepal@GLWD.org or 212-294-8165.

Now that we have your attention, did you know that members can listen to archived webinars for FREE CEUs?
The Academy recently announced a new activity type for fulfilling CPE requirements. It’s called a Recorded Pre-Approved CPE, and should be added to your log under Activity Type 175.

This new activity will allow you to download and listen to archived webinars without the requirement of a post-test. In order for a presentation to be eligible for credit, the activity must meet the following criteria:

- Must be prior-approved for this activity type;
- Must be listened to within one year of the live presentation.

This is a great opportunity to get CEUs without hassle. However, be aware that RDNs can claim no more than 15 CEUs under this activity type in a recertification cycle (five-year period). DIFM is now in the process of getting approval for our archived webinars. We will update membership when they are available. At that time, a certificate of completion will also be available for download.

These webinars will also be available to non-DIFM members for a fee.

For more information, log on to integrativerd.org, click the Learn tab, then CPE Center tab.
References:


32. Victoria J. Drake, Ph.D. Multivitamin/mineral supplements. Linus Pauling Institute Oregon State University
2011;21(8):891-896.
Questions – Using Dietary Supplements in Practice

Choose the one best answer to each question.

1. Which of the following does not meet the definition of a dietary supplement?
   a. Echinacea tincture
   b. Sublingual liquid melatonin
   c. Glutamine powder
   d. Intra-nasal vitamin B12

2. The dietary supplements most commonly linked to safety concerns are:
   a. Goldenseal, St. John’s wort and methylcobalamin
   b. Bee pollen, probiotics and DL-alpha tocopherol
   c. Ergogenic, weight loss and sexual enhancement aids
   d. Ephedra, pyridoxal 5’-phosphate and magnesium sulfate

3. Which of the following are regulated by the Good Manufacturing Practices (GMPs)?
   a. Quality control procedures, testing of final products, manufacturing operations
   b. Design and construction of the physical plant, structure/function claims, and testing of incoming ingredients
   c. Supplement facts panel, testing of in-process materials and handling consumer complaints
   d. Product formulation, maintaining records and maintenance and cleaning procedures

4. Under DSHEA, the FDA has the authority to:
   a. Set formula standards
   b. Approve product claims
   c. Take ineffective products off the market
   d. Audit and inspect manufacturers

5. Due to a potential drug-nutrient interaction, which of the following supplements may be indicated in patients taking statin medications?
   a. Coenzyme Q10
   b. Vitamin B12
   c. Calcium
   d. Magnesium

6. Which of the following is an active form of a B vitamin?
   a. Cyanocobalamin
   b. Methyltetrahydrofolate
   c. Pyridoxine hydrochloride
   d. Thiamin

7. A high quality MVI should contain which of the following?
   a. 7 of the 8 isomers of synthetic vitamin E
   b. DL-alpha tocopherol
   c. Chelated vitamin E
   d. Mixed tocopherols

8. Which of the following is an example of a chelated mineral?
   a. Zinc oxide
   b. Ferrous sulfate
   c. Magnesium aspartate
   d. Calcium carbonate

9. What are two of the most important factors to consider when choosing omega-3 fatty acid supplements?
   a. Cost and form
   b. Purity and stability
   c. Dose and source
   d. Oxidation and concentration

10. Which of the following functional medicine tests may be helpful when assessing a patient’s need for probiotics?
    a. Comprehensive digestive stool analysis
    b. RBC fatty acid profile
    c. Micronutrient analysis
    d. Nutrigenomic testing
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*Refer to your Professional Development Portfolio Learning Needs Assessment Form (Step 2)*
Upcoming Conferences and Meetings

October 12-13 (La Jolla, CA) and November 16-17 (Baltimore, MD), Ayurveda Training for Health Professionals: Prevention, Diagnosis and Treatment in Maharishi Ayurveda. www.clinical-ayurveda.org/index.html

October 24-26, 7th Annual Probiotic Symposium. San Antonio, TX. www.probioticsymposium.com/


October 27-30, American College of Lifestyle Medicine Annual Conference. Crystal City, VA. www.lifestylemedicine.org/events


What’s New in Print–Journal Reviews

Food allergy risk in infants

In a case-control study, infants fed a diet of fresh, unprocessed foods were found to have a lower risk of developing food allergies. Mothers kept food diaries for the infants from birth to one year of age; 41 infants with food allergies were compared to 82 age-matched controls. There were significant dietary differences between the groups. A diet high in fruits, vegetables and homemade foods was associated with lower risk of food allergies by the age of two.


Epigenetics and health

Epigenetic marks turn our genes off and on, influencing which proteins are made at specific times. When methyl groups attach to a gene, the gene turns “off,” or becomes less active. Likewise, when acetyl groups attach to a gene, the gene turns “on,” or becomes more active. Some epigenetic marks are permanent, whereas others come and go. What makes them appear and disappear? Factors such as diet, stress, weight, tobacco or chemical exposure play a role in activation and deactivation. Scientists hope to eventually alter risk of disease through manipulation of epigenetic marks with diet or medication. Diseases such as cancer, obesity and Alzheimer’s disease are being investigated, but research is still in its fledgling stages.


The gut microbiome

Registered dietitians should be aware of dietary influences on gut microflora and gastrointestinal health. Gut microflora contributes to overall health in many ways, including boosting immunity, preventing pathogenic bacteria from gaining a foothold and synthesis of B vitamins and short chain fatty acids. Although in its infancy, research has linked gut microflora to type 2 diabetes, obesity and, possibly, cancer. A high fiber, plant-based diet has been shown to best support healthy gut microflora. Researchers hope to determine through diet how to promote growth of specific gut bacteria to obtain targeted health effects. Gut Microbiota World Watch has a helpful and informative website: www.gutmicrobiotawatch.org/, provided by the European Society for Neurogastroenterology & Motility.


Bt maize: consumption by pigs during gestation and lactation has no allergic or inflammatory effects.

Twenty-four sows raised on non-genetically modified (GM) feed were randomly assigned to either a Bt maize diet (Bt MON810 maize,
expressing the Cry1Ab protein) or a non-GM, non-Bt maize control diet on the day of insemination. Diets were fed throughout pregnancy and lactation. Blood was sampled from sows at time of insemination (day 0), days 28 and 110 of gestation and day 28 of lactation. Blood and tissue were sampled from offspring at birth. There were no significant differences in cytokine production between Bt-maize and control groups. Analysis of immune cells indicated some significant differences in various white blood cell counts and percentages. However, the authors state that these differences are not likely caused by an allergic response, as neither the Cry1Ab protein nor Cry1Ab protein-specific immunoglobulins (IgA and IgG) were detected in Bt-maize fed sows or offspring. The authors conclude, “Bt maize is unlikely to pose any risk to pig health, even following long-term consumption and a similar response could be expected in humans.”


GMO risk assessment in the European Union

Genetically modified microorganisms (GMMs) are regulated in the European Union. Before commercialization is permitted, products containing GMMs are evaluated for human, animal and environmental safety by the Scientific Panels of the European Food Safety Authority (EFSA). There are four classifications of GM products, ranging from chemically defined compounds without recombinant genes to those containing viable GMMs. The classification of the product determines which legislative process and regulations apply. When evaluating products, the EFSA considers peer-reviewed research, compares the potential adverse effect of the GMM to its parent non-modified organism (“conventional counterpart”), and may request experimental data if needed. While GMM-produced food enzymes have been available for many years, the authors note, “to date, there is no food containing GMMs or derived from GMM biomass commercially available in the EU.”


Commentary: GM foods, cancer and diet

Genetically manipulated foods have been available for millennia, if one considers plant breeding and saving seeds from the strongest crop. Genetically-modified foods have been commercially available for years and eaten by millions without harmful effects to health or the environment. The evidence for a causal relationship between GM foods and cancer has not been borne out in studies of strong experimental design. There are already many carcinogens in our food supply that are dose-related, e.g. nitrates in lunchmeats, bisphenol A in canned foods, benzopyrenes in charred meats. Those concerned with cancer risk would do better to limit these known carcinogens, avoid carcinogenic behaviors, e.g. smoking, excess alcohol intake, and consume fresh foods—genetically modified or not.


Review: GM plants and safety

A thorough safety assessment of GM foods intended for human consumption has never been conducted. This systematic review is an update to the authors’ previous review published in 2006. It focuses on GM plants only and covers the period of January 1980-August 2010. While the number of total citations has increased since 2006, there were no new studies relating to potential adverse health effects of GM potatoes, cucumber, tomatoes, sweet pepper, peas and canola. There was new information for GM corn, soybean and rice, which is reviewed within. However, many studies were not specifically designed to assess toxic effects of the GM product. Nine studies concluded that GM corn was as safe as its non-GM counterpart, but three studies presented concerns regarding specific varieties of GM corn. Research was also divided as to the safety of GM soybeans and rice. It is noted by the authors that, “…most of the studies demonstrating that GM foods are as nutritional and safe as those obtained by conventional breeding, have been performed by biotechnology companies or associates, which are also responsible of commercializing these GM plants.” The authors recommend further research be conducted to assess the long term effects of diets containing GM products and the possible additive effects of these foods.


HOT Nutritional Genomics Research Publications, August 2013


A two-page listing of genes and gene variants which are tested by various direct-to-consumer testing companies is provided. This balanced review describes the issues and concerns surrounding personalized nutrition, including ethics, and urges the involvement and education of health professionals to help guide the proper translation and appropriate utilization of such testing.

Situating nutri-ethics at the junction...

The use of nutrigenetics, nutrigenomics, and nutri-proteomics to optimize nutrition is discussed, including ethical considerations regarding its potential for enhancing sports performance.


Carrying these higher-risk gene variants while consuming higher levels of red meat was associated with a 3.4-fold increased risk of developing colorectal cancer in this study.


Discusses opportunities and challenges for nutrigenetics, nutrigenomics, epigenetics and metabolomics in the 21st Century. (A free PDF copy of this article can be obtained via the PubMed page by clicking on “LinkOut - more resources” near the bottom -- in contrast to most other free articles which have links near the upper-right corner of their respective PubMed pages.)


A review of published studies on nutritional genomics knowledge and confidence among nutrition and dietetic professionals indicates that related education and strategies for improving education are still weak. An approach for improving genetics-related education is suggested.


Discusses the importance of public acceptance and engagement. Because many members of the public would like to involve their primary health professionals, better education and familiarization among professionals will be important. Behavioral changes among the public are crucial to its successful implementation, with those who are already suffering symptoms being among the most motivated. Further research on implementation is warranted since personalized nutrition has considerable potential for reducing non-communicable diseases.


Use of health recommendation systems by members of the public are influenced by many factors, including enjoyment. However, when health professionals are also involved, greater emphasis is placed on usefulness. Partnering between the public and professionals may be important for the successful embrace of personalized nutrition.


Although some maintain that the science is still too immature, others contend that enough information already exists to warrant individualized nutrition advice that may diverge from general dietary recommendations. Ethical considerations are discussed, including the advantages of a cautious approach, while also avoiding paternalism.


Various approaches to personalized nutrition are described, including phenotype, metabolotype (based on metabolites), and genotype. Embracement of personalized nutrition will depend on consumer demand, which may occur first for things like weight management, or in connection with the use of dietary supplements. A European initiative, Food4Me, will be issuing reports on efficacy, ethics, and consumer attitudes.


Although calcium may help protect against colorectal cancer, higher calcium intakes among African American men was associated with an increased risk of prostate cancer in this study, especially among those with enhanced intestinal absorption of calcium (i.e., those who carry two copies of the Cdx2 variant of the VDR gene).

Inquiries about above references? Please contact Ron L Martin, MS, President, Nutrigenetics Unlimited, Inc.; ron@nutrigenetics.net. Please check out www.isnn.info/ to learn more about the dietitian membership discount.
In order to fully appreciate this book, it is important to recognize the credentials of the author. Vandana Shiva is a philosopher, physicist, and a world renowned environmental activist. She is a tireless champion for bioethics, preservation of biodiversity, environmental conservation and women’s rights and has received over 20 international awards for her work. In 1991, she started an organization called Navdanya with the goal to protect native seeds and promote organic farming and fair trade. She acts as a government advisor in her home country of India and for many governments around the globe. She is fearless in her pursuit of justice and gives a voice to those who are voiceless in what she calls the seed wars and the war against the earth. Making Peace with the Earth is not an easy read. Vandana exposes, in painful detail, multiple examples of corporate injustice, cultural destruction and ecological disaster that results from what she calls “eco-apartheid” where humans see themselves as separate from, and above the laws of nature.

The first part of the book outlines the variety of ways corporations are able to privatize natural resources such as land and water and details the human and cultural impact as people are forced to give up their livelihood and way of life.

According to the author, instead of living within our natural limits, the human demand for resources has exceeded the capacity of the earth by 20% and we are living above the biosphere’s ability to renew. This is particularly concerning as China and India become increasingly industrialized. Vandana describes the corporate growth model as one that is dependent on debt—both ecological and financial—that is ultimately unsustainable.

In the second part of the book, she describes the global food crisis as being fueled by monocropping, the practice of growing the same crop on the same land, year after year, and the production of commodity foods, most of which are used to feed animals and create biofuels. Around the globe, plant biodiversity and the nutritional content of foods is declining while the use of agricultural chemicals continues to increase. Vandana describes how farmers are becoming indebted to companies for the purchase of patented (genetically engineered) seed strains and chemicals that are ruining their land and their lives.

She argues against the claims that genetic engineering helps reduce the need for agricultural chemicals and dramatically increases crop yields. With references and examples, she describes the increase in resistant agricultural pests and the potential for negative environmental and health effects from growing and eating genetically modified organisms.

In the end, Vandana briefly describes her vision for a better future—one that is dependent on our collective awareness and action. By shining light on the injustice and inequity, she hopes to fuel a passion for change. Her vision includes a shift from consumerism and consumption to compassion and conservation. Her hope is that someday nations will be judged on their Gross National Happiness vs. their Gross National Product and that people will make sustainable and equitable business decisions and will live within the limits of the earth.

While she doesn’t offer any specific suggestions for how to make this happen, one could assume it is up to each individual to examine their own consumer habits and commit to some form of grassroots activism. Vandana’s voice is heavily academic and the writing is dense. I would recommend this book to anyone who wants a well-documented reference on the current state of the global corporate economy and its wide reaching effects on the environment, the climate, our food supply, and the overall well-being of the human race.

Vandana Shiva is a driving force in the environmental movement. In the words of Jane Goodall, UN Messenger of Peace: All of us who care about the future of Planet Earth must be grateful to Vandana Shiva. Her voice is powerful, and she is not afraid to tackle those corporate giants that are polluting, degrading and ultimately destroying the natural world.

Reviewed by Kelly Morrow, MS, RD

Making Peace with the Earth
Vandana Shiva
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The Integrative Approach • FNCE 2014

New for 2014! FNCE is setting sessions into educational tracks during the proposal submission process. There are 15 tracks, and the Committee for Professional Development has developed and approved a track for Integrative and Functional Nutrition called Emerging Integrative Approaches for Nutrition and Dietetics.

The deadline to submit an Educational proposal for the 2014 event in Atlanta, Georgia (October 18-21) is November 15, 2013.

It’s exciting that one entire track has been devoted to integrative and functional nutrition, and in order for this track to be a success, it’s important that the Academy gets a wide variety of submissions, thus we are calling on members to submit proposals. Topics can include: recent news on integrative and functional nutrition therapies, digestive health, detoxification, inflammation, elimination diets, food allergies and intolerances, integrative nutrition-focused physical, food addictions, mind body therapies, nutrigenomics/nutrigenetics, dietary supplements, and translating the latest information to clients.

For more information, including tips for development, links to the proposal site and submission guidelines, please visit:
http://www.eatright.org/fnce/sessionproposals/