

Position of the American Dietetic Association: Fortification and Nutritional Supplements

ABSTRACT

It is the position of the American Dietetic Association (ADA) that the best nutritional strategy for promoting optimal health and reducing the risk of chronic disease is to wisely choose a wide variety of foods. Additional nutrients from fortified foods and/or supplements can help some people meet their nutritional needs as specified by science-based nutrition standards such as the Dietary Reference Intakes. Dietetics professionals are trained to assess dietary adequacy as well as the need for dietary modification. This position paper addresses increasing the nutrient density of foods or diets through fortification or supplementation when diets fail to deliver consistently adequate amounts of vitamins and minerals. The discussion presents points to consider that relate to both public health and individual applications. Many resources may be used to help guide the dietetics professional to determine responsible, evidence-based recommendations relating to nutrient fortification or supplementation.

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POSITION STATEMENT

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This position* paper is written for practitioners and policymakers and takes into account the rapid changes in both patterns of fortification and prevalence of use of dietary supplementation that include vitamins and minerals (1). Emerging scientific evidence and new products in the marketplace blur the distinctions between fortified foods, nutrient-containing dietary supplements, dietary supplements with other bioactive in-

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gredients, and drugs. Although limited in scope to vitamins and minerals, the concepts outlined in this paper relate to other nutrients such as proteins and amino acids, fatty acids and other lipids, and dietary fiber. Furthermore, much of the discussion about nutrient supplements applies to dietary supplements containing other bioactive substances. Because this field of research is so active, dietetics professionals will need to adapt the concepts presented in this paper to the evolving understanding of optimal nutrition.

NUTRIENT-DENSE FOODS WITHIN AND AMONG THE BASIC FOOD GROUPS

Before considering fortification and supplementation, one must acknowledge that a balanced variety of nutrient-dense foods eaten in moderation lays the foundation of a health-promoting diet. Nutrient-dense foods are "those foods that provide substantial amounts of vitamins and minerals and relatively few calories" (2). Most of the nutrients that a person consumes should come from a variety of foods and beverages, because they provide vital macronutrients and micronutrients, including water and dietary fiber, as well as pigments and other useful nonnutrient components (3-7). Diets rich in a variety of foods within and among the basic food groups support nutritional balance and supply nutrients that cannot be added to foods or nutrient supplements at optimal levels. For example, relatively large nutritional requirements for major minerals with distinctive flavors such as magnesium present major formulation challenges for food scientists and supplement makers. In other instances, toxicologic thresholds and the narrow ranges that exist between some trace minerals' Recommended Dietary Allowances (RDAs) or Adequate Intakes (AIs) and Tolerable Upper Intake

Levels (ULs) preclude their addition to foods (eg, copper, selenium) (8). A comparison between the levels of minerals in whole-grain flours and enriched wheat flours illustrates the importance of including basic foods in the diet (3). Despite the useful contributions of fortified foods and nutrient supplements that this paper will define, a diet composed solely of such products does not replace the established or yet-to-be-defined benefits provided by a diet that includes a variety of foods within and among the basic food groups (3,5).

REGULATORY FRAMEWORK FOR SUPPLEMENTATION AND FORTIFICATION

The essence of the legal definition of a dietary supplement is as follows:

A product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin or mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract; or combinations of these ingredients. And a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form; and a product that is not represented for use as a conventional food or as a sole item of a meal or the diet; and a product that is labeled as a dietary supplement (9).

Fortification means the addition of nutrients to foods, including beverages, and is used synonymously with "enrichment" (10). Since the 1940s, policymakers at the Food and Drug Administration (FDA) interpreted the food law and determined that fortification in the United States should not be required; rather, nonenriched counterparts to enriched standards of identity still exist (11). However, the FDA does regulate how much of which nutrients must be added to enriched foods, such as infant formula, fortified milk, or foods that contain olestra fat-replacement as a food additive (10,12). Other than applications defined by the FDA, fortification is voluntary and discretionary (11). In 1980, the FDA codified a nonenforceable Fortification Policy that sets forward principles for the rational addition of nutrients to foods (10). These principles include, in part, adding nu-

trients to correct dietary insufficiencies; restoring nutrients lost during storage, handling, or processing; and adding 5% of the Daily Reference Value or Reference Daily Intake per 100 kcal for a full range of nutrients (10,11). Although the FDA cannot force manufacturers to comply with its Fortification Policy, the agency does enforce the truthfulness and accuracy of food labeling of all fortified foods. In 2003, a committee of the Food and Nutrition Board proposed a different rationale for discretionary fortification that will be discussed later in this paper (11).

In the United States, the FDA regulates both fortified foods and dietary supplements in accordance with the Federal Food, Drug, and Cosmetic Act (9,13,14). Unlike other countries, the United States regulates both categories as foods (15); conventional foods include fortified foods, whereas dietary supplements form a separate category of foods. Despite the potentially vague delineations between foods and dietary supplements, regulations mandate that most packaged conventional foods bear "Nutrition Facts" labeling; dietary supplements also bear nutrition labeling in the form of a "Supplement Facts" panel on their labels (13,14).

FORTIFICATION AND SUPPLEMENTATION: MODIFYING THE NUTRIENT DENSITY OF THE DIET

The first two key recommendations for the general population from the *Dietary Guidelines for Americans 2005* state, "Consume a variety of nutrient-dense foods and beverages within and among the basic food groups..." and "Meet recommended intakes within energy needs by adopting a balanced eating pattern..." (2). Health statistics indicate that many people in the United States are overweight, yet undernourished (3-5,16-21). These people consume more calories than they need without meeting recommended intakes for several nutrients (3). One way to help these individuals is to improve the nutrient density of their diets. For purposes of this discussion, nutrient density is a relational term and is defined as "the ratio of the amount of a nutrient in foods to the energy provided by these same foods" (22). Therefore, a more vitamin- and mineral-rich diet rela-

tive to its caloric content has a higher nutrient density (3). Even when the diet is fully adequate and balanced, nutrients that are added through fortification or supplementation increase the nutrient density of the diet. The balance of this section outlines several points to consider when modifying the nutrient density of the diets of populations and individuals.

Food Security Deserves Attention

A laudable goal for public health practitioners and policymakers is to have everyone in the population consume the RDA or AI for each nutrient without exceeding its UL (3,11). However, experts indicate suboptimum nutrient intakes by the US population (3). Specifically, an assessment of available data concluded that low reported intakes of vitamin E, calcium, magnesium, and potassium are of concern for both children and adults; levels of dietary vitamins A and C are also low among adults (3). Subpopulations that consume inadequate levels of vitamins and minerals will be discussed later. Since 1974, data from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) have shown that increasing the nutrient density of diets, which includes fortified foods, improves the health status of participating at-risk women, infants, and children (23).

Sedentary Lifestyles and Low Energy Intakes Present Challenges

In the increasingly sedentary American society, people require less energy to maintain a healthy body mass index. To counteract this societal change, the *Dietary Guidelines for Americans 2005* advise, "To help manage body weight and prevent gradual, unhealthy body weight gain in adulthood: Engage in approximately 60 minutes of moderate- to vigorous-intensity activity on most days of the week while not exceeding caloric intake requirements" (2). This position is consistent with the Food and Nutrition Board recommendation that individuals get at least 1 hour of physical activity each day to obtain sufficient nutrients from food and drink, and stay in energy balance (24). A complementary approach is to add nutrients to, which increases the

average nutrient density of, the standard American diet (4,5,25).

Optimal Intakes May Be Higher than Previously Recognized

Advancements in basic sciences are necessary to further the applied science of nutrition. In its early decades, nutrition research focused on fairly simplistic outcomes that could be demonstrated relatively quickly (26). The expanding knowledge of molecular biology, genetics, and proteomics is setting the stage for explosive growth in the understanding of nutrition (27,28). As new data are published, more sophisticated theories emerge while old more simplistic one-deficiency-disease-per-nutrient paradigms falter (5,6,26-29). A newer theory, “fetal origins of adult disease,” suggests that maternal nutrition status may affect the genome of the fetus, thereby influencing the offspring’s development and life-long risk of disease (28,30).

Separately, consider the recent theme that indicates that an array of separate diagnoses may share common causes (6,26,27,29,31). One emerging example points to data published since the Dietary Reference Intakes (DRIs) were issued in 1997 for vitamin D (32): suboptimal vitamin D status may be more widespread than previously thought, because the vitamin’s functions involve more than bone mineral metabolism (3,18,26,31,33,34). Researchers speculate that suboptimal serum 25-hydroxyvitamin D-3 may increase the risk of some forms of cancer (18,26,31,33,34) or exacerbate a variety of autoimmune dysfunctions (31) such as rheumatoid arthritis (35), type 1 diabetes (33,34), multiple sclerosis (31,34,36), and thyroid dysfunction (34). Although it is premature to make recommendations for vitamin D for these conditions, additional research will clarify its role. By improving the nutritional status of the vulnerable but sizeable subpopulations, the prevalence of debilitating diseases may decline and the average health span could increase (18,26,27,33). Fine-tuning a person’s diet based on that individual’s nutritional requirements—which are still being defined through scientific discovery—offers the potential of slowing the onset of multiple chronic diseases by minimizing the effects inflammation and DNA damage or slowing

mitochondria’s functional deterioration with aging (6,26,27). More research is needed to further our understanding of every facet of “optimal” nutrition.

Nutrient Modifications Can Improve Health Status of Subpopulation Groups

Some subpopulations are particularly vulnerable to inadequate nutrient intake for a variety of physiological, psychological, and socioeconomic reasons (4,5,16,25,37). For example, public health measures such as WIC for those in lower-income households show improved iron status among participants (16,23). Among 2- to 4-year-old children, WIC food packages intend to focus on iron, vitamin E, and potassium (16); WIC-eligible adolescents and women should focus on foods that include calcium, iron, magnesium, potassium, folate, and vitamins A, B-6, C, D, and E (16).

For some people with underlying health conditions, foods and supplements containing specific nutrients could be contraindicated.

Adjusting the density of the diet for one or more nutrients may help protect subpopulations from environmental challenges that they encounter resulting from dietary, occupational, lifestyle, or pharmacologic exposures (25,27). To illustrate this point, a brief overview of nutrient–drug interactions in the *Merck Manual of Diagnosis and Therapy* explains that common pharmaceuticals such as oral contraceptives may increase the need for zinc, folic acid, and vitamins B-6 and B-12 (38). Apart from the many environmental influences on nutritional status, conclusions of recent literature reviews identified nutritional needs of several subpopulations that warrant careful attention (3):

- iron—adolescent females and women during childbearing years;
- folic acid—adolescent females and women during childbearing years;

- vitamin B-12—people >50 years old; and
- vitamin D—elderly people, people with heavily pigmented skin, and people exposed to inadequate ultraviolet-B radiation.

Individualized Diets Help People Meet Specific Needs

Through appropriate and targeted assessment and coordination with the client’s physician, practitioners can tailor diets to improve health. Medical nutrition therapy and nutrigenomics (how nutrition affects genetic expression) can promote peak performance. Biochemical researchers show clearly how, on a molecular level, dietary or nutrient changes can shift a person’s homeostatic balance toward more health-promoting outcomes (26-28). Furthermore, diet modifications can aid the expression of favorable genetic phenotypes and help suppress the expression of unfavorable genes (27). For example, up-regulating methylation with folic acid and vitamins B-6 and B-12 corrects homocystinemia in genetically susceptible individuals (26,27,29).

Proper Assessment Needs to Guide Selection and Use of Fortified Foods and Nutrient Supplements

When positioned in a suitable context, both conventional and emerging assessment techniques help determine whether a specific formulation or application of a fortified food or nutrient supplement could be beneficial or potentially detrimental (11). A periodic, evidence-based assessment is a responsible, systematic approach to take (7,39,40).

Special needs of individual clients or patients. Characteristics commonly found in elderly people, such as declining renal function or atrophic gastritis, may influence micronutrient use and clearance (37). This is but one example of the importance of using effective assessment to guide food choices; there are many others. For some people with underlying health conditions, foods and supplements containing specific nutrients could be contraindicated. For instance, individuals who are homozygous for hemochromatosis should avoid iron-rich foods and supplements (1,41). Patients undergoing renal dialysis must carefully monitor their mineral

status (1,42). However, researchers still seek definitive answers to questions such as, “Whether and how should smokers modify their intake of antioxidant vitamins?” and “While persons are undergoing radiation therapy, which nutrients should they increase or limit?” Research that further elucidates dietary adequacy must continue (11,22,37).

Form and source of the nutrient. Dietetics practitioners should understand and address the differences among various forms and sources of nutrients when counseling clients and patients. This is not to suggest that one form or source of a nutrient is necessarily good or bad, or right or wrong in every situation, but rather that one may function differently from another. Four factors that relate to different facets of bioavailability deserve special consideration (22):

- All forms of a nutrient may not function equivalently. For example, data published, especially since the publication of the 1997 DRIs, indicate that vitamin D-3 delivers far more vitamin D activity than vitamin D-2 (1,34).
- Research indicates that natural sources of nutrients are not always the most biologically effective (29). Although natural source d- α -tocopherol delivers twice the vitamin E activity as its synthetic dl- α counterpart (1), synthetic folic acid is widely considered more bioavailable than natural sources of folate (43). Regardless, healthful diets that feature a variety of nutrient-dense foods often include nutrients from both natural and synthetic sources.
- Sources of nutrients in a food matrix might perform differently from their isolated counterparts, depending on the nutrient and the dietary context. Calcium citrate malate added to vitamin-C-rich orange juice has been shown to be easily absorbed, but the overall nutritional impact of the fortified juice is obviously not identical to that of milk (1,3). Separately, vitamin E added to fortified cereals was shown to be more readily available than the same amount taken in capsule form (44). Heme iron is considered more bioavailable than many iron salts (1). On the other hand, foods that contain calcium,

phytic acids, tannins, or polyphenols tend to bind or compete for the absorption of non-heme iron, making it less available (1).

- Nutrient balance must be preserved. Some products in the marketplace feature a single added nutrient, whereas others deliver an array of vitamins and minerals. Examples of products that provide relatively high levels of a single nutrient include juice beverages that are fortified with 100% of the Daily Value for vitamin C, and iron supplements. An alternate approach combines many nutrients in a single product, such as fortified ready-to-eat cereals and multivitamin supplements. Since the passage of the Dietary Supplement Health and Education Act of 1994, many product introductions feature small combinations of nutrients that offer structural or functional benefits, such as antioxidant protection. Of course, synergistic and antagonistic nutrient-nutrient interactions—such as the well-documented interaction between zinc and iron—may influence the overall nutrient balance of the diet and the physiologic value of any food or supplement (1). Therefore, with so many facets to consider, practitioners need to assess their clients and patients periodically and to determine whether, and which forms and sources of, nutrients are appropriate. Resources listed in Figures 1 and 2 may help guide the assessment process.

Potentially beneficial or harmful interactions with drugs. Use of prescription drugs and polypharmacy increases with age and chronic illness (19). Although interactions with foods and other nutrients have been discussed elsewhere in this paper, one must also consider interactions with drugs or botanicals. Drugs with narrow therapeutic windows, such as warfarin, are particularly sensitive to fluctuations in intakes of nutrients like vitamins E or K. Nutrients and drugs may interact in other ways. For example, corticosteroids have been shown to increase the need for calcium and possibly vitamin D (1). Well known to many, some diuretics used to treat hypertension require compensatory potassium, whereas others are potassium-sparing. By working with knowledgeable dietetics professionals

and physicians, individuals can strive to fit their diet and drug regimens around important aspects of their lifestyles instead of forcing their lifestyles to be completely dictated by their medications or dietary restrictions (5).

Consumption patterns that help deliver nutritional benefits. With a few exceptions, most vitamins and minerals are absorbed in the small intestine. Therefore, people should ingest and digest foods and dietary supplements in ways that will maximize the likelihood of absorption. The optimal consumption pattern depends on the nutrient, dose, and form. Nutrient supplements should be consumed in a way that will enhance absorption, typically with food (1,45). For example, the absorption rate of vitamin E is higher when it is consumed with dietary fat (1,45). When evidence exists that more thoroughly defines the effective use of a product, it benefits both the manufacturer and consumer to label such information.

NUTRIENT FORTIFICATION: SPECIAL ASPECTS

When to Support Nutritional Fortification

To comply with regulations and government policy. Food fortification can be a cost-efficient way of increasing the nutrient density of a population's diet (46). As our understanding of vitamin nutrition blossomed in the late 1930s, the US military documented that recruits suffered from clinical nutrient deficiencies. Since 1941, governmental and voluntary programs added nutrients such as thiamin, riboflavin, niacin, and iron to flour and other grain-based products (10,11). Decades of evidence document that enrichment programs such as these effectively reduce the prevalence of classical nutrient deficiency diseases in populations around the world (46). Beginning in 1998, mandatory levels of folic acid added to enriched grain-based products lowered the prevalence of neural tube defects in the United States and Canada (26,43,47,48). In a separate successful initiative, the US government recognizes that iron-fortified foods largely account for WIC participants' improved iron status (23).

To address inadequate nutrient intake in large segments of the population. Consistent with the key recommendation of the *Dietary Guidelines for Americans*

Resource	Web site	Comments
ADA Code of Ethics	www.eatright.org/Public/Other/index_adacode.cfm	The code establishes the general framework of ethical standards and scope of practice. State licensure provisions may offer further guidance to practitioners.
A Healthcare Professional's Guide to Evaluating Dietary Supplements	www.pharmacist.com/pdf/dietary_supplements.pdf	ADA and the American Pharmaceutical Association published a roadmap for evaluating dietary supplements. It does not reflect the current regulations, but it offers useful assessment criteria.
Guidelines for the Recommendation or Sale of Dietary Supplements	www.eatright.org/Public/GovernmentAffairs/index_6332.cfm	ADA's House of Delegates first approved the document in 2002. It outlines many criteria to consider when recommending or selling dietary supplements. Some of the concepts also apply to fortified foods.
American Dietetic Association Practice Paper "Dietary Supplements"	www.eatright.org/Public/GovernmentAffairs/index_21828.cfm	Publication that provides practical guidance to practitioners.
ADA Evidence-Based Library and other tools for weighing the totality of the evidence	adaevidencelibrary.com/default.cfm (available to ADA members)	User-friendly summaries of the latest nutritional research and guides that help apply evidence-based medicine to one's practice.
ADA Position Papers	www.eatright.org/Member/PolicyInitiatives/index_21012.cfm	Several position papers provide useful, pertinent insights on matters relating to fortification and supplementation within the context of diverse topics.
<i>Journal of the American Dietetic Association</i>	www.adajournal.org	The <i>Journal</i> routinely publishes new evidence on relevant topics.
Continuing Professional Education (CPE) opportunities	www.eatright.org/Public/ConferencesAndEvents/96_11613.cfm	CPE expands professional understanding.
Nutrition in Complementary Care dietetic practice group (NCC)	www.ComplementaryNutrition.org	NCC promotes the integration of conventional nutrition practices with evidence-based alternatives through education, research and practice.
ADA publications	www.eatright.org/Public/ProductCatalog/104.cfm	Several books pertain to nutrient fortification and supplementation.

Figure 1. Resources available through the American Dietetic Association (ADA) that pertain to increasing the nutrient density of the diet through nutrient fortification or supplementation.

2005, fortified foods are nutrient-rich. Therefore, the general population benefits from having a variety of fortified foods available from which to choose. Many breads, cereals, and certain beverages are fortified with vitamins and minerals. Food labels can help guide food selection. Beyond the value of fortified foods to the general public, three categories of subpopulations benefit from food fortification:

- One subpopulation represents those who follow certain dietary regimens for reasons of health or lifestyle. For example, those who consume vegetarian diets can choose fortified plant-based foods such as ready-to-eat cereals or cereal bars to obtain nutrients that naturally come from animal sources, such as vitamins B-12 and D.
- A second category of key subgroups relates to age and stage of the life-cycle (11). Fortified foods can help people meet elevated nutritional needs, such as iron and folic acid for women of childbearing age, or vitamins D and B-12 for older individuals (3,29,48). Fortified foods can also help subpopulation groups fill nutritional gaps left by their typical food choices (3). Although it is desirable for adolescent females to consume adequate amounts of calcium-rich foods, the reality is that most fall far short of the goal (1); calcium-fortified foods can help close the gap (16,18,20,49).
- The third category of subpopulations that benefits from fortified foods includes those that involve prevalent diseases or conditions, such as iron-deficiency anemia (1,16,23), bone loss (18,49), or perhaps autoimmune dysfunction (26,34). From a historic per-

Resource	Available at:	Comments
National Institutes of Health, Office of Dietary Supplements	http://ods.od.nih.gov/	Web site supplies information and resources for education, assessment, and research.
US Food and Drug Administration, Center for Food Safety and Applied Nutrition	www.cfsan.fda.gov/	Web site provides regulatory and other information about foods, including dietary supplements.
Agency for Healthcare Research and Quality	www.ahrq.gov/	Agency prepares and publishes evidence-based technology assessments, reports, and practice guides related to supplement efficacy and safety.
<i>Cochrane Systematic Reviews</i>	www.cochrane.org/index0.htm	Cochrane Reviews provide assessments of current evidence relating to specific health conditions.
PubMed	www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=Details&DB=pubmed	PubMed provides abstracts from published literature. Although they lack important detail, they indicate the general direction of the studies' results. Also, abstracts provide information to obtain the entire paper or to contact the paper's authors.
<i>Natural Medicines Comprehensive Database</i>	www.naturaldatabase.com/	Fully referenced rating of the safety, efficacy, uses, and interactions of over a thousand natural substances, including all the vitamins and minerals.
Manufacturers of nutrient supplements and fortified foods	An Internet search of contact information printed on package labels can often identify alternative contacts and other useful information.	Manufacturers know thoroughly the products they sell and may have a dietetics professional on staff. Dietetics professionals and consumers can ask the manufacturer for more detailed information about its products; representatives of responsible companies are often willing and able to provide evidence-based research that addresses the professional's questions.
Reputable trade organizations	There are many. Two examples in the nutrient supplements area include the Council for Responsible Nutrition (www.crnusa.org) and the National Natural Foods Association (www.nnfa.org/facts/)	Trade organizations offer perspectives that typically include evidence-based research to support or refute positions taken by policymakers and other organizations.
Allied health professions and other organizations	Two of many examples include the American Academy of Pediatrics (www.aap.org/) or the World Anti-Doping Agency (www.wada-ama.org/en/). Links available from Council for Responsible Nutrition (www.crnusa.org/pdfs/CRN_SNS_OrgsPositions0204.pdf)	Position statements reflect the current thinking of professionals in their fields of expertise.
Tufts Nutrition Navigator	navigator.tufts.edu	The site rates the quality of nutrition-oriented Web sites.

Figure 2. Examples of resources that pertain to increasing the nutrient density of the diet through nutrient fortification or supplementation.

spective, voluntary fortification began in 1924 for this reason with the iodization of salt to prevent or treat goiter (11), followed in the 1930s with vitamin-D–fortified milk to prevent rickets, which was previously prevalent (11).

Special Considerations Associated with Nutritional Fortification

The nutrient profile of a food with discretionary fortification depends on several factors, including the nutritional status of the population that it

reaches, which was discussed elsewhere in this paper (11).

The dietary context. For decades, fortified foods fit predictably within a few specific product categories, such as milk, cereals, and juice drinks (3). More

recently, nutrients are being added to energy bars, chewing gum, and other new entries in the marketplace (43). As new nutrient-dense, fortified foods become available, dietetics professionals can ask a few questions to determine whether and when such foods would be appropriate for their patients and clients. If a food has not had a long tradition of fortification, does it substitute for another nutrient-rich food, perhaps one that has been fortified through the years? Is the food typically eaten at a certain meal, as a snack, as a meal replacement, or paired with other foods? Does the nutritional profile of the fortified food fit within the context of how the food is commonly eaten? The nutrient profile and labeling of ready-to-eat cereals reflect the fact that they are typically paired with milk. Dietetics professionals must stay mindful of current dietary patterns and continually monitor food labels because nutrient databases do not include the most up-to-date nutrition information for every product, plus the published literature relating to consumption patterns typically lags behind the data collection by several years (43,50,51).

Technical feasibility. In addition to the dietary context, one must consider the sensory properties of fortified foods. Unlike most nutrient supplements, food is chewed, savored, and enjoyed. Therefore, formulators of fortified foods must overcome many technical challenges of delivering appetizing, good-tasting nutrition (52). If a manufacturer fails to make nutrient additions that are acceptable to consumers, the product will not be successful in the marketplace. Furthermore, fortified foods must maintain their nutritional and sensory qualities throughout the stated shelf-life (ie, the “sell by” or “best if used by” dates printed on packages). To slow oxidative rancidity, antioxidants like vitamin E (sometimes labeled as mixed tocopherols) may be added to keep products fresh as well as to make a nutritional contribution.

Implications of reducing levels of nutrient fortification. The rarity of classical nutrient-deficiency diseases in the United States may be the direct result of effective enrichment and fortification practices (11,43). Regardless, some believe it may be appropriate to scale back enrichment and fortification practices in the United States. In

2003 a committee of the Food and Nutrition Board proposed lowering the Daily Values used for nutritional labeling (11,53). The committee recommended moving away from the historical application of RDAs to a lower population-weighted calculation of the Estimated Average Requirements (11). Before making such a major policy change, policymakers must analyze the impact on the public’s health, especially for the vulnerable population groups identified earlier in this paper (11,16,43). As explained earlier, policymakers must consider new scientific learning that occurs subsequent to the publication of the current DRIs (16).

New technologies. Advances in research and development will certainly lead to novel forms of nutrient delivery. For example, if new varieties of folate-rich grain are developed using conventional cross-breeding techniques, would growers and consumers embrace the new dietary source of folate (54)? How would this “biofortification” technology impact the traditional methods of fortification or supplementation? Similarly, recombinant DNA technology may potentially modify the nutritional profile of food crops or remove allergenic properties. How would such changes alter the population’s overall nutritional status? Consumers can now fortify their own foods with nutrients such as iron and vitamin C by sprinkling the contents of single-portion sachets into foods (55). How will newer delivery systems for nutrients impact traditional techniques? Dietetics professionals and policymakers must continuously monitor new developments and evaluate how they may impact current fortification and supplementation practices.

NUTRIENT SUPPLEMENTATION: SPECIAL ASPECTS

Although food fortification practices impact public health more broadly, most uses of nutrient supplements address individuals’ specific needs.

When to Consider Supporting Nutrient Supplementation

To follow expert recommendations for subpopulations. Examples in four types of circumstances illustrate when nutrition experts, professional organiza-

tions, or governmental agencies recommend nutrient supplementation. Each circumstance reflects a change in either a person’s typical nutritional needs or his/her eating patterns.

- The first example relates to certain dietary regimens. Experts acknowledge that when adults ingest fewer than 1,600 kcal per day, they have a low probability of getting adequate vitamins and minerals solely from food (3,25). Physicians overseeing dietary regimens such as modified fasts routinely prescribe vitamin and mineral supplements.
- The second category considers stages during the life cycle. For instance, most protocols for the care of pregnant women include a specially formulated prenatal supplement that contains higher levels of folic acid and iron (1), and oftentimes calcium along with a complement of other vitamins and minerals. Elderly people, having lower rates of nutrient use and often compromised diets, are more at risk for suboptimal nutrition, especially as their caloric intakes decrease to $\leq 1,500$ kcal/day (25).
- The third category addresses using supplements to prevent, treat, and/or manage diseases or other conditions. Some of the many examples that illustrate this point include: (a) supplementation with vitamin D for the prevention of rickets (26,56) or perhaps some autoimmune disorders (31,34), (b) electrolyte replacement in the treatment of acute diarrhea (57), (c) the important role of nutrient supplementation in the management of renal dialysis patients (42), and (d) the addition of nutrient supplements to ensure nutrient adequacy for people on low-calorie weight-loss diets (3).
- The fourth type of circumstance reflects an emerging philosophy: to supplement the diet as a public health measure for large subpopulation groups. One such case is in recognition of the importance of adequate folic acid status during the first weeks of pregnancy to prevent neural tube defects. In this instance, the Surgeon General recommends that all women of child-bearing age—whether or not they plan on becoming pregnant—should sup-

plement their diets with folic acid (58).

To address an individual's nutrition needs that are not being met through foods. Similar sets of circumstances as described in the preceding paragraph determine an individual's need for nutrient supplementation.

- Dietary regimens that limit variety in food selection represent the first category. To illustrate this point, vegans or people who eliminate all dairy foods from their diets often find it difficult to ingest adequate levels of nutrients such as calcium or vitamin D (1,7); supplementation may be a logical alternative, especially if they lack exposure to good-quality sunlight (3,18,26,31).
- Certain life stages compose the second category. As the gastrointestinal function of otherwise healthy elderly individuals slows, nutrients from food may not be adequately absorbed or metabolized. Supplementing the diet with nutrients such as crystalline vitamin B-12 may be warranted if serum levels decrease (3,7,29,37,59).
- The third category is medical nutrition therapy associated with specific diseases or conditions. For example, people with allergies often turn to nutrient supplements because their food choices may be severely restricted. Those with celiac disease typically use supplements to fill the nutritional gaps caused by the malabsorption or the dietary elimination of so many grain-based and other gluten-containing foods; mineral supplementation further addresses anemia and bone health, which is often compromised in patients living with celiac disease (1,60). Separately, certain genetic diseases or undesirable polymorphisms may be treated through nutritional supplementation at levels higher than ingested from typical diets (27).

Precautions Associated with Nutrient Supplementation

For whatever reasons individuals take dietary supplements, they should inform their health care providers and strive for consistency to achieve the intended outcomes. Con-

sistency is especially important when people take pharmaceutical agents that may interact with nutrients being taken as dietary supplements.

Need for careful product selection. As mentioned earlier, forms of nutrient supplements can vary widely. Supplements are often available in a variety of forms, sources, and potencies. Because regulations require that product labels indicate the specific ingredients and the level of each dose, consumers are able to select the same form of supplements at each purchase. For best results, consumers should buy supplements that deliver consistent quality over time. Although reputable brands may cost more, clients should choose supplements that have recognized quality-control procedures in place. Until the FDA finalizes current good manufacturing practices for dietary supplements (rule proposed in March 2003) (13), the National Sanitation Foundation International (61), the US Pharmacopeia (62), the Australian Therapeutic Goods Administration (63), and the National Nutritional Foods Association (64) are organizations that offer frameworks for supplement quality. Alternatively, manufacturers may pay to have their products tested for label compliance and have the results posted on the ConsumerLab.com Web site (65). People with paid subscriptions to the site can learn the names of products that comply with their label claims. Selecting supplements that deliver consistent quality is the first major step toward consistent use of supplements.

Importance of consistent intake. Standardizing the frequency and the method or pattern of consumption contribute to one's ability to predict the supplement's overall effect on the body. For example, an individual absorbs less calcium if he or she takes an entire day's dose of calcium at one time instead of taking the same total amount in divided doses ≤ 500 mg throughout the day (1). Experts recommend that individuals establish a consistent time for taking nutrient supplements, often with the same meal each day. Regardless, individual response to a nutrient supplement such as vitamin E can vary widely from person to person (44).

Consider the impact of all sources of nutrients. Caregivers of very young children, and others who include a variety of nutrient-dense foods in their typical food patterns, should periodically review the need to take nutrient supplements (43). In some instances, particularly with fat-soluble vitamins such as preformed vitamin A or trace minerals, people can reach or possibly exceed their ULs (66). In other cases, some physicians recommend that elderly patients take two multivitamin supplements each day as a way to ingest adequate levels of vitamins D and B-12 (66). People in situations such as these may be at particular risk of hypervitaminosis A (66). As stated before, adequate nutritional assessment is vital.

Inform health care providers. People should report the use of any and all supplements to their health care providers. Because neither physicians nor nurses routinely ask patients about diet or supplement use, dietetics professionals are best suited to ascertain a client's supplement use at the same time as they learn about his or her dietary patterns and medications. Responding effectively to the information gleaned from the client may prove vital to a successful outcome.

Concentrated sources. Because nutrient supplements are concentrated sources of nutrients that typically are not chewed or accompanied by either water or macronutrients, they pose a greater risk than food sources for toxicity, interactions with other nutrients or drugs, and adverse reactions. In some instances, the FDA requires special packaging and labeling to minimize the risk of unintended overdose (10,13). People should carefully monitor consumption of dietary supplements and keep them stored out of the reach of children. Medical supervision is appropriate when a person consumes fat-soluble vitamins or minerals at levels greater than the RDAs (4,5). The consumption of pharmacologic doses of nutrients in excess of their RDAs is not discussed here. However, some propose reducing the UL for certain nutrients such as vitamin E (67). Dietetics professionals who recommend dietary supplements must critically evaluate the ever-emerging evidence, particularly the data relating to higher doses.

Reporting adverse effects. If a dietary supplement is suspected of causing a serious adverse event, the FDA encourages health care professionals and consumers to file a voluntary report through the agency's MedWatch program at 1-800-332-1088, or online at www.fda.gov/medwatch (68). If preferred, a person may complete the Form 3500 and submit it online, via facsimile at 1-800-332-0178, or via mail at: MEDWATCH, The FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

USE OF FORTIFICATION AND SUPPLEMENTS IN THE ABSENCE OF ESTABLISHED PROTOCOLS

The need to conduct research to support an evidence-based practice persists in order for us to better comprehend the economic and health implications of altering the nutrient density of foods or diets through fortification and supplementation. Nearly every research paper identifies unanswered questions; some publications lay out particularly insightful recommendations and perspectives (3,11,22,37,43,69).

With an ever-evolving understanding of nutrition, how should dietetics professionals determine whether, when, and how to put new knowledge into practice? How complete must the evidence be or how overwhelming must the consensus become before an individual embraces a point of view (7,26,69,70)? Although these questions relate to all facets of dietetics, this discussion focuses solely on issues surrounding fortification and nutrient supplements. Dietetics professionals have the training and skills to determine when the evidence warrants integration into their practices.

One familiar tenet, "do no harm," resonates whenever a practitioner approaches the outer limits of her or his comfort zone. When do practitioners place their clients and patients at higher risk by not putting into practice newer ideas that have not achieved universal acceptance (31,67)? Dr Walter Willett observed that nutrition recommendations evolve slowly, "[Policymakers] say, 'You really need a high level of proof to change the recommendations,' which is ironic, because they never

had a high level of proof to set them" (26,71). Yes, the quantity and quality of evidence must be convincing; dietetics professionals must critically evaluate all of the relevant evidence before applying it to practice, making sure the recommendations fit within their own professional comfort zone (70). However, instead of waiting for leaders in other professions to state their positions on matters involving diet and nutrition, dietetics professionals have the ability to accept their leadership role, to critically assess all of the evidence, and to act accordingly. Furthermore, dietetics professionals can exert their leadership roles by petitioning organizations and governmental agencies to embrace an evidence-based decision-making philosophy.

Because nutrient supplements are concentrated sources of nutrients that typically are not chewed or accompanied by either water or macronutrients, they pose a greater risk than food sources for toxicity, interactions with other nutrients or drugs, and adverse reactions.

The ADA and the Commission for Dietetic Registration provide tools that help guide members through their discernment process. Figure 1 summarizes many of the resources offered by the ADA and the Commission for Dietetic Registration.

Beyond the information provided by the ADA, professionals can find other useful resources on the Internet and elsewhere to help with the critical evaluation of the massive amount of information that exists on the topics of fortification and supplementation. Several examples are listed in

Figure 2. Aspects relating to safety, efficacy, form, level and mode of administration, selection criteria for research subjects, research design, sensitivity and magnitude of results, and stated research hypotheses all deserve special attention.

By keeping abreast of the rapidly expanding science and by maintaining questioning yet open minds, discerning dietetics professionals who apply evidence-based techniques to their practices are well positioned to build on previously acquired knowledge and skills to lead the future of dietetics with respect to nutrient fortification and supplementation.

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