

# Measuring vitamins and minerals in dietary supplements for nutrition studies in the USA

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**Abstract** This article illustrates the importance of having analytical data on the vitamin and mineral contents of dietary supplements in nutrition studies, and describes efforts to develop an analytically validated dietary supplement ingredient database (DSID) by a consortium of federal agencies in the USA. Preliminary studies of multivitamin mineral supplements marketed in the USA that were analyzed as candidates for the DSID are summarized. Challenges are summarized, possible future directions are outlined, and some related programs at the Office of Dietary Supplements, National Institutes of Health are described. The DSID should be helpful to researchers in

assessing relationships between intakes of vitamins and minerals and health outcomes.

**Keywords** Dietary supplements · Dietary supplement ingredient database · Multivitamin mineral supplements · Analytical values

## Introduction

There are many reasons why data are needed on the vitamins and minerals in dietary supplements. Consuming

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too much or too little of these essential micronutrients can harm health, so estimates of intake must be accurate. Dietary supplements are widely consumed and frequently measured in various types of nutrition studies. Information on the vitamin and mineral contents of supplements is needed for sound estimates of exposures to them, to calculate total nutrient intakes, and to understand the associations between exposures, health, and disease. Also, consumers and health care professionals seek accurate information on the vitamin and mineral compositions of dietary supplements.

#### Current status of information on vitamins and minerals in supplements

Currently, analytically validated information on the vitamin and mineral contents of foods is relatively complete, while that for dietary supplements is meager. Analytical information on the compositions of foods and beverages is readily accessible on the internet [1], but analytically validated data on vitamins and minerals in dietary supplements are fragmented and not widely available. This paucity is a matter of immediate practical importance because complete estimates of nutrient exposure level must be based on accurate information on intakes of vitamins and minerals from dietary supplements as well as from foods, beverages, and medications. The accuracy of intake estimates may be poor if dietary supplement label databases are used due to the questionable validity of ingredient information on product labels. Both random error and bias in the actual

means compared to label values may occur. The extent of deviation between the label values of dietary supplements and their actual contents has not been studied extensively in the US, and gaps remain in the analytical literature. However, because of US regulatory requirements that label values reflect minimum contents of nutrients, deviations in actual nutrient content from label values are usually thought to tend toward overages. Overages may be larger for some vitamins—particularly those that are less stable and more likely to deteriorate with a long shelf life, those that have other functions (such as antioxidants) in the product itself, or vitamins that are relatively inexpensive—than for minerals [3]. Therefore, analytically validated dietary supplement databases are needed.

#### Bias and levels of micronutrients in food and supplements

Variability refers to the disparity between ingredient amounts listed on the product label and the actual composition of the product. Even highly variable analytical data on the micronutrient compositions of foods and dietary supplements are helpful in obtaining more precise estimates of individuals' total nutrient exposures and their responses to different doses. Only a few studies in the peer-reviewed literature have compared labeled versus analyzed values in dietary supplements, but preliminary results suggest that more are needed. The variability in the vitamin and mineral contents of foods and dietary supplements is considerable, and can exceed 10–20% or even more for an individual nutrient [2, 3]. In contrast, for prescription drug products,

**Table 1** Definition of dietary reference intakes used in the US and Canada

Term and abbreviation	Definition	Uses
EAR: Estimated Average Requirement	Average daily nutrient intake level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group	For individuals, used to examine the probability that usual intake is inadequate For groups, used to estimate the prevalence of inadequate intakes within a group
RDA: Recommended Dietary Allowance	The average daily nutrient intake level sufficient to meet the nutrient requirements of nearly all (97–98%) of healthy individuals in a particular life stage and gender group	For individuals, usual intake at or above this level has a low probability of inadequacy For groups, the RDA should not be used to assess intakes of groups
AI: Adequate Intake	A recommended average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate; used when an RDA cannot be determined	For individuals, usual intakes at or above the AI have a low probability of inadequacy For groups, mean usual intake at or above this level implies a low prevalence of inadequate intakes
UL: Tolerable Upper Intake Level	The highest average daily nutrient intake level 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 increases	For individuals, usual intake above this level may place an individual at risk of adverse effects from excessive nutrient intake For groups, the UL is used to estimate the percentage of the population at potential risk of adverse effects from excessive nutrient intake

the variability between label declarations and actual composition may be smaller. Drugs must meet different standards, often have fewer ingredients, and the methods used are often developed by the patent holder or manufacturer.

#### Vitamin and mineral intakes from food and supplements in American diets

Table 1 summarizes the dietary reference standards used in the United States and Canada, referred to as the dietary reference intakes (DRI) [4]. These serve as guidelines for nutrient intakes from food and supplements that are considered to be adequate for healthy persons. Inaccurate estimates of population intakes might result in inappropriate interventions and policy recommendations, and without estimates of the contribution of dietary supplements, intakes of many key nutrients could be grossly underestimated. For example, Table 2 shows that in the 2001–2002 National Health and Nutrition Examination Survey the US adult mean intake from food alone fell short in vitamins A, C and E, and that calcium intake fell short of adequate intake (AI) levels among most females [5]. For

vitamin C, although the average intakes from food were 105 mg for males and 84 mg for females, 40% of the population in both genders consumed less than the Estimated Average Requirement for vitamin C, which was 75 mg for males and 60 mg for females. The adult multivitamin most commonly reported in the National Health and Nutrition Examination Survey contains 60 mg vitamin C, and if the entire population were to take this amount, it would contribute considerable amounts of this vitamin, which might benefit individuals whose intakes from food alone were below the estimated average requirement (EAR). Additional examples are provided for vitamins E, A and calcium.

The effects of multivitamin–mineral supplements on total nutrient intakes vary, depending on the population [6]. Table 3 provides an example of data on vitamin B12 and folic acid intakes from foods as well as dietary supplements among adults 71+ years of age in a recent National Nutrition and Health Examination Survey. Those who needed dietary supplements the most because their food intakes fell short of recommendations for these vitamins were not necessarily those who actually took

**Table 2** Comparison of mean intakes of adults of 19+ years of age from foods alone in the National Health and Nutrition Survey 2001–2002, and the effect of adding a commonly consumed multivitamin supplement

Nutrient	Recommended Dietary Allowance (RDA) or Adequate Intake (AI)	Estimated Average Requirement (EAR)	Percent of adults whose intake from food alone was less than or equal to the EAR or AI from food alone	Tolerable upper level (UL)	Intake per day of adults of 19+ years of age from food alone, mean (median)	Potential intake if supplement taken contained amount of nutrient contained in most commonly consumed multivitamin/mineral supplement in the National Health and Nutrition Examination Survey	Total intake, food plus supplement
Vitamin C (mg)				2000		60	
Males	90	75	40%		105.2		165.2
Females	75	60	40		83.6		143.6
Vitamin A, micrograms, retinoic acid equivalents (RAE)				3000		1050	
Males	900	625	57		656		1706
Females	700	500	48		564		1614
Vitamin E (mg TE)				Not available		13.5	
Males	15	12	89		8.2		21.7
Females	15	12	97		6.3		19.8
Calcium (mg)	(AI)	Not applicable		2500		162	
Males	1000–1200		63		984		1146
Females	1000–1200		88		735		897

**Table 3** Usual intake of vitamin B12 (mcg) from food and supplements for adults aged 71 and over, data from National Health and Nutrition Examination Survey 1999–2002

Source, micrograms	Mean	Median	Percentiles				
			15th	25th	50th	75th	85th
Foods	4.3	3.1	0.9	1.6	3.1	5.2	6.7
Supplements	35.4	Not available	Not available	Not available	Not available	6.8	24.5
Both foods And supplements	38.5	6.7	1.5	2.6	6.7	18.6	28.7

supplements of these nutrients. This is a common finding in such studies [7].

### Development of an analytically validated Dietary Supplement Ingredient Database (DSID)

The Office of Dietary Supplements co-sponsored a conference in 2002 to assess the future needs for research in surveys of nutrient intake from foods and dietary supplements [8–11]. Web links are available for the summaries of this and another workshop the Office of Dietary Supplements held in collaboration with Federal and non-Federal partners to explore research needs for assessing dietary supplement intake [12, 13]. The 2002 conference provided an opportunity to assess the state of the science with respect to current survey methodology, data needs, and the analyses required to describe usual dietary intake from foods and dietary supplements. A major conclusion of the conference was the recognition that accurate measures of intake would depend on analytically substantiated values for the ingredient content in dietary supplements. As a result, ODS established an Inter-Agency Agreement with the Agricultural Research Service of the USDA to fund the development of a dietary supplement ingredient database that will ultimately be integrated with food composition databases. The Nutrient Data Laboratory at the USDA is working with the Office of Dietary Supplements to plan and develop the DSID.

#### Development of validated analytical methodologies

Foods and dietary supplements are regulated differently in the US than they are in Europe and many other countries. In the US, the regulatory category into which products fall is determined by the intended use of the product. The Dietary Supplement and Health Education Act of 1994 was significant because it established dietary supplements as a separate legal category and defined a framework for Food and Drug Administration regulation of this category. It also established the regulatory framework for supplements as foods, not drugs, set rules for what information labels must contain, and gave the Food and Drug Administration the

authority to write supplement-specific Good Manufacturing Practices (GMPs) based on a food model. Therefore, multivitamin–mineral supplements are regulated as foods and mandatory registration or certification of dietary supplement ingredient contents is not required. International standards such as the Codex Alimentarius [14] and standards of the European Union now regulate multivitamin–mineral supplements as foods, as is done in the United States [15–17].

For most dietary supplements, few analytically validated values are available, even for vitamins and minerals, and label declarations are used as surrogate indicators of supplement composition. In order to produce analytical data to populate a DSID based upon chemical analysis, appropriate reference materials and validated analytical methodologies are essential. To have access to these resources, DSID developers drew extensively on a complementary ODS effort, the Dietary Supplement Analytical Methods and Reference Materials Program [18, 19]. This ODS program funds the development of both reference materials and analytical methodologies for products of interest.

Because dietary supplements have matrices, excipients, and other factors that may differ from those used in foods, it cannot be automatically assumed that chemical methods developed for foods are appropriate for dietary supplements. Numerous analytical methods for vitamins and minerals in foods were already available from AOAC International [20] and specific methods for some vitamins (including multivitamin–mineral supplements) were available from the US Pharmacopoeia [21, 22]. Analytical methods from both groups were evaluated for their suitability for the purposes of the DSID. ODS and the Food and Drug Administration partnered with the AOAC International through its Official Methods program to improve methods of dietary supplement analysis. Through it, analytical methods were validated for  $\beta$ -carotene, and they are currently being validated for vitamin E. AOAC International named B vitamins among the nutrients of highest priority for method validation, and mentioned that biotin was also of interest. Standardized methods were developed and some are now available to analyze DSID

priority micronutrients, which include vitamins A, B1, B2, B6, B12, C, D, E, K, biotin, beta carotene, folic acid/folate, lutein, niacin, pantothenic acid, and the minerals calcium, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, and zinc.

The USDA's Agricultural Research Service Food Composition Laboratory and Nutrient Data Laboratory and other DSID collaborators reviewed the current status of analytical methods that existed for vitamins and minerals in dietary supplements and assessed the quality of data received from several laboratories in a pilot study. Comprehensive criteria for evaluating methodology using the criteria for qualitative, quantitative and economically reasonable analyses have been published for foods [22, 23]. A method was defined as qualitative if it was capable of separating the target food components and of detecting a useful signal from each component. Methods were defined as quantitative if they were capable of providing the accuracy, precision, and detection limits required for the target food components at their naturally occurring levels in commonly consumed foods. Methods were defined as economical if determinations could be made at a high rate with low cost. Methods being used for nutrients in dietary supplements were categorized into three groups: "adequate and robust" (those meeting all three of the criteria); "adequate but limited" (meeting two of the criteria); and "inadequate" (for those failing to meet two or more of the criteria). In a preliminary assessment for nutrients in dietary supplements, most minerals had analytical methods that were robust or adequate; vitamins were more variable. Specific methods and laboratories were determined to be acceptable or unacceptable for future work on this project [24].

#### Development of appropriate reference standards

Standard Reference Materials (SRM®s) help to confirm that an individual laboratory's analytical method provides accurate results, both during method development (validation) and as part of routine use of the method (quality assurance). A multivitamin mineral supplement certified reference material (SRM 3280® Multivitamin/Multi-element Tablet) was developed in a partnership between ODS and the US National Institute of Standards and Technology (NIST), and values will be assigned for more than 30 vitamins, minerals, and carotenoids in this material using several methods, some of which include the use of stable isotopes as internal standards. A calcium carbonate SRM already exists and is available from NIST. NIST has developed a material for  $\beta$ -carotene and tocopherols, and is developing other materials for tocopherols and tocotrienols as well.

#### The Dietary Supplement Ingredient Database (DSID)

The ultimate goal of the DSID project is to develop an analytically validated database of representative nutrient values for dietary supplement products including chemical analyses of the individual ingredients in supplements and indicators of data quality [26]. One of the primary uses of this database is to estimate intake of nutrients and other dietary supplement ingredients in the diets of Americans. This estimate can then be combined with nutrient intakes from foods to better estimate total dietary intake. This section describes the process used to date in developing the DSID and populating it with data for vitamins and minerals.

One of the main requirements for the development of an accurate database for supplement content is a comprehensive quality control program for the analytical data. A sound analytical quality control (QC) program begins with the selection of qualified laboratories. A limited number of laboratories are available in the US with the capability of and an interest in analyzing vitamins and minerals in dietary supplements.

A two-step process was used in collaboration with the ARS contracts office to determine which of the high-performing laboratories would be qualified to perform contract work for future studies. Technical proposals were rated on technical approach, in-house quality control plan, past performance, and organizational qualifications. The laboratories which were found to be acceptable were then sent samples of known analytical composition. Laboratories that showed accurate results were eligible for analytical contracts for those components where they demonstrated acceptable performance.

#### Pilot studies with DSID

The objectives of the pilot studies were to obtain analytical information on the vitamins and minerals in adult multivitamin–mineral supplements, which are the most commonly used dietary supplements in the US, and to prepare for a systematic survey of dietary supplement composition.

#### Multivitamin–mineral supplements

There is no regulatory or generally accepted definition of a multivitamin–mineral supplement product. Many multipurpose multivitamin–mineral supplements contain several fat-soluble vitamins, seven or more water-soluble vitamins, and seven or more minerals. For research purposes, some uniformity in ingredients is needed in order to conduct comparisons among products studied for nutritional and other purposes.

Daily values (DV) are the reference daily values used in the US for nutrition labeling purposes. The term is used on food or dietary supplement product labels to describe the recommended levels of intake of a nutrient. The percent daily value (% DV) represents how much of a nutrient is provided in one serving of the food or dietary supplement. For example, the DV for calcium is 1,000 mg (milligrams); a food that has 200 mg of calcium per serving would state on the label that the % DV for calcium is 20%. In the pilot studies described below, USDA defined multivitamin mineral supplements as containing more than two vitamins to identify representative products. In the second study of 35 adult multivitamin mineral supplements sold in the USA, USDA determined that all 35 products contained nine or more vitamins and from one to thirteen of the minerals having a defined %DV. However, there is no definition or categorization scheme that is suitable for all purposes. For example, when the broad definition of multivitamin–mineral supplements as used in the %DV pilot study was used, several multivitamin–mineral supplement specialty products were chosen that had three or more vitamins and minerals but not the entire range of vitamins or minerals. These products, although labeled as multivitamin–mineral supplements, were typically designed and marketed to address specific health concerns, such as bone health, eye health, or to provide high levels of antioxidants.

#### Uniformity of multivitamin mineral supplement composition

In addition to the variability in vitamin and minerals found in products labeled as multivitamin mineral supplements, the quantity of each vitamin and mineral present can vary considerably. Thus, the consistency of multivitamin–mineral supplement composition varies both from nutrient to nutrient and in terms of the amount of each within the product. Furthermore, the brands sold and the compositions of multivitamin mineral supplements sold in various marketing channels (e.g., pharmacies, supermarkets, warehouse stores, multilevel marketing direct and internet sales, and nutrition or health food stores) appear to differ markedly.

#### Multivitamin–mineral supplement composition determined from label values in the % daily value pilot study

The first challenge that became apparent in preliminary studies was that there were differences between brands of dietary supplements sold in the US in their vitamin and mineral contents as well as in the amounts and forms of these micronutrients that were present. A sampling plan was needed to select a group of products that were representative of what was on the market.

A second challenge was the issue of how well actual composition matched the label declaration on multivitamin–mineral supplement products. In the US, regulations require that the actual nutrient contents of products be equal to or greater than the declared level on the label, after taking into account processing effects and shelf life losses [3]. A recent study of analyzed values for folic acid in 29 US breakfast cereals ranged from 98% to 320% of label values [27]. Trade associations in the United Kingdom identified overages for dietary supplements consistent with good manufacturing practices that varied depending on the vitamin in question [28]). Failures to meet declared label values have also been reported in US products [29]. For dietary supplements and many processed foods that lack analytical data on vitamins, intake estimates obtained from product label declarations may be a source of bias [30]. For minerals, excess amounts with large overages are probably less likely because of their increased bulk and shelf life stability, but little publicly available data other than a recent study on iron [27] and two others on selenium [2, 31] currently exist on these questions. Using label declarations as surrogates for analytical values will have different meanings in different countries. For example, European Commission regulations require that label values reflect the average content of the marketed product, although some overages may be added in anticipation of shelf life losses [17].

To address these issues, USDA scientists began a pilot study of products in the marketplace, their composition and the analytical accuracy of label composition data. The first pilot study was conducted to provide preliminary information regarding the accuracy of label information for the most commonly used multivitamin–mineral products in the US, thereby allowing ODS to gauge the need for an analytic database for these supplements [25]. Comparisons of label statements with analytical values developed from these and other studies in the DSID can be used to determine if, as is likely, there is an overage in vitamins or minerals.

The %DV pilot study used the National Health and Nutrition Examination Survey 2001–02 data containing label data on adult multivitamin–mineral supplement products commonly reported over the last 30 days in the US. A total of 541 products were identified. For the purpose of this study, multivitamin–mineral supplements were defined as a pill, capsule, or gel cap containing three or more vitamins. The adult multivitamin–mineral supplement products were sorted by nutrient, nutrient amount and weighted frequency of use. Frequency distributions of declared label values for selected nutrients were determined, and the most common %DV levels were identified. Although there were dozens of levels of specific nutrients in reported multivitamin products, three or four levels were

the most common [25]. Products from each of the most common %DV levels ( $n=3$  or  $n=4$ ) were randomly selected and purchased for each of the 23 nutrients for a total of over 200 products. Samples were sent to qualified laboratories for analysis. Results generated from these samples are being analyzed and will be published separately.

#### Representative sampling plans developed for an adult multivitamin–mineral supplement study

The objective of the second adult multivitamin–mineral supplement pilot study was to obtain a representative sample of these products on the market and to determine their vitamin and mineral contents by chemical analysis. Current market data were cross-referenced with national survey records to identify 35 popular adult multivitamin–mineral supplement products in the US. A nationwide sampling program was designed to select sample units from various marketing channels. The multivitamin mineral supplements in this study were statistically designated for purchase in specific market channels, since multivitamin–mineral supplements used by consumers are obtained from a variety of diverse sources.

Samples of the multivitamin–mineral supplements were sent to the laboratories for analysis of 22 vitamins and minerals, evaluating six lots of each product from different geographic regions of the US. Rigorous quality control measures were implemented. Data are now being evaluated.

#### Comparisons of %DV on labels with analytically determined values

Originally it was hoped that it would be possible to predict actual (e.g., analytically determined values) values in a multivitamin–mineral dietary supplement product or group of products from analyzed values in the same category. In practice, this has proven difficult since dietary supplement products and nutrients in the multivitamin–mineral supplement category are so heterogeneous.

The data will be compared to results from the ongoing analytical study of 35 popular US multivitamin–mineral supplements to evaluate whether these nutrient patterns are consistent. Statistical evaluation of analytical results from both studies for each nutrient is in progress. Factual information on product labels, including the nutrient pattern (components and labeled levels), nutrient form, and any quality certifications will be considered for grouping similar products. These groupings may be helpful for examining relationships for each nutrient between actual levels and labeled levels. Documenting the manufacturer or type of manufacturer (based on size, location, private label or brand

name) of analyzed products may identify distinct formulation patterns.

### Other challenges in developing the DSID

#### Sampling

Developing an analytically verified DSID requires representative samples of products. This is challenging not only because dietary supplements are marketed in multiple channels, but also because of several other factors identified below. The DSID working group has used national survey data, chiefly the most recent National Health and Nutrition Examination Survey data available, as well as market research firms to identify representative products. Representative lots are identified for purchase by including appropriate market distribution channels and geographic regions of the country in the sampling plan. The types of products sold vary considerably by market channel. Regions of the country vary not only in terms of regional brands of dietary supplements that are sold, but also in terms of climactic circumstances that may affect micronutrient levels. Also, dietary supplement formulations can change often, with ingredients being included or excluded or quantities of ingredients being altered, making frequent sampling necessary. Product nutrient content changes occur more rapidly than they do for many whole foods in the food supply. The supplement marketplace is constantly changing and evolving, and what is analyzed may not be exactly what people are contemporaneously consuming. In choosing samples of dietary supplements, shelf life must be taken into account since some nutrients deteriorate over time. The time elapsed between the product's manufacture and consumption needs to be ascertained; since expiration dates are not particularly useful in this regard.

With respect to sampling, depending upon the objective of the study, multistage statistically based sampling plans can be developed to select sample units representative of the US market place for any specific class or category of supplements. No single sampling process meets all user needs. The data needed for nutrition research and consumer information purposes are quite different. For example, researchers may want to know not only the representative average values but the variability, bias, quality and source of the data, while for consumer information purposes approximate values within an acceptable range of deviation from the dietary supplement label values will suffice. If the purpose is quality control or certification of product amounts, as it is for the US Pharmacopoeia standard [21], a great deal more information on product characterization may be needed. For regulatory pur-

poses, the Food and Drug Administration in the US requires that products provide at least 100% of the declared value, but no requirements on upper limits for dietary supplement ingredients have been specified. It is the manufacturer's responsibility to ensure that the supplement product, as formulated and marketed, is safe under label conditions of use. For compliance purposes Food and Drug Administration requirements vary; for some types of compliance such as hazards, analysis of a single product used by an injured consumer may be sufficient; for other types of compliance many samples may be needed.

#### Development of appropriate analytical methods

For some nutrients such as vitamin B12, folate and vitamin D, consensus is still lacking on the most appropriate and cost-effective analytical methods to use. Among the many other analytical challenges are deciding how to deal with issues such as different matrices (water vs. lipid solubility), encapsulated products, variations in formulation, whether the analyses assess and separate the different bioactive forms of the micronutrient, and whether different forms are bioequivalent. Sample preparation methods may vary from those used in foods [32]. Because levels of vitamins and minerals in dietary supplements cover an enormous range of levels, the sensitivity of the analytic method must also be evaluated.

#### Other ingredients

Subsequent studies are planned using the DSID for the analysis of specialty adult multivitamin–mineral supplements (such as children's products) and calcium products, including antacids. Nutrients and other ingredients to be analyzed in further studies include other single- and double-nutrient supplements (especially vitamin D products).

Exposure to botanicals may also be related to health outcomes. Botanical ingredients will be studied after validated analytical methods and reference materials for them are made available. There are great analytical challenges in measuring amounts of bioactive constituents such as botanicals in dietary supplements. For some botanicals, the active ingredients are often unknown or uncharacterized, or analytical methods are unavailable. Other programs at ODS are attempting to fill these gaps, but the task is formidable. Efforts of private and voluntary agencies must augment those of government to complete the work in a timely fashion.

#### Future directions

The ultimate structure of the DSID also needs further consideration. For example, the National Health and

Nutrition Examination Survey's list of dietary supplements covers only a portion of the products in the marketplace. Should it include estimates both from the dietary supplements in the National Health and Nutrition Examination Survey and also for other dietary supplements based on USDA market-based surveys of products? Whether the DSID should include brand name, generic and default products, and whether codes will be used to identify data types and sources (analytical, label and manufacturer data) is not yet decided. The definitions and categories used in the DSID will also need further refinement. The most appropriate and user-friendly ways to harmonize the DSID with the food database need consideration. These questions will be addressed as research proceeds.

#### Other relevant research

Other relevant research at the ODS involves two dietary supplement label databases; the National Health and Nutrition Examination Survey dietary supplement label database, and a database of labels of all dietary supplements sold in the US [21].

#### The National Health and Nutrition Examination Survey dietary supplement label database

The National Health and Nutrition Examination Survey tracks dietary supplement use in the United States via a population-based survey to assess the health and nutritional status of 5,000 noninstitutionalized adults and children from 15 communities nationwide each year. As an interim measure, until analytically validated databases are available, ODS has supported the National Center for Health Statistics in the creation of a database of dietary supplement labels and the collection of information on supplement use in the National Health and Nutrition Examination Survey [33]. This allowed detailed analysis of dietary supplement use to be made, beginning with the National Health and Nutrition Examination Survey of 1999–2000, and for total intakes of nutrients from foods and dietary supplements to be better estimated, considerably improving nutrient exposure estimates [34]. The dietary supplement database from the surveys is released to the public every two years, and it should prove useful to researchers for other purposes as well.

#### Database of all dietary supplement labels in the US

The National Health and Nutrition Examination label database only covers dietary supplements taken by respondents to the National Health and Nutrition Examination Survey, and since the data releases are in two-year cycles, approximately two years after collection, information is not

always available on newer products. Therefore, this label database, while a useful source of data, is not sufficient by itself. No existing label database captures all dietary supplements in the US. ODS is currently exploring the feasibility of developing one that can be used by researchers to assess product use or nutrient or dietary supplement ingredient intakes by participants in research studies. There has been considerable agreement among government, industry, and academic stakeholders for several years that a national dietary supplement database would support and enhance research activities [8–11]. Fragmentary databases for specific purposes currently exist from various sources, but none of the current information available represents most or all dietary supplements sold in the US. ODS is now investigating the feasibility of the design, development, implementation, maintenance, and enhancement of a new, web-based application for cataloging all dietary supplements sold in the US in a dietary supplement label database. A single, publicly available and easily accessible electronic database with complete and comprehensive label information for dietary supplements—including lists of ingredients, amounts of ingredients, manufacturer information, etc.—can serve multiple research and educational needs. The National Health and Nutrition Examination Survey contains the most relevant data available for a dietary supplement label database and so the initial system will be populated with information from the National Health and Nutrition Examination Survey if time and funds permit.

## Conclusions

The need is evident for analytically validated vitamin and mineral values in dietary supplements for use in nutrition studies and for consumer information purposes. Much is planned and underway, and soon more definitive data will be available. The DSID represents a fledgling effort to fill this need, but private and voluntary sector groups must join in the effort if the momentum is to be sustained and the work extended to other nutrients and botanicals.

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