Preliminary Comparison of Labeled Levels Ranges for 21 Vitamins and Minerals in representative adult multivitamin/mineral products purchased for analysis for the Dietary Supplement Ingredient Database (DSID) study

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DSID Dietary Supplement Ingredient Database
A U.S. Government Initiative

ABSTRACT:

The Nutrient Data Lab (NDL), Beltsville Human Nutrition Research Center (BHNRC), in collaboration with the Office of Dietary Supplements, has developed an analytically-based Dietary Supplement Ingredient Database (DSID). A follow-up adult MVM study is planned to add ingredients (Vitamins A and D, and chromium) not published previously and to monitor other ingredients and ingredient levels since the original study (2006-2007). In both studies, data from NHANES (National Health and Nutrition Examination Survey) and NMI (Nutrition Marketing Institute) were used to identify representative products and a statistical sampling plan was developed. Products were purchased nationwide in three market channels (mass market, natural/health food and direct). Percent daily value (%DV) and per serving ingredients levels, obtained from label supplement facts panels, were recorded. After the labeled levels were compiled for 21 ingredients, ingredient ranges were compared to the ranges for products purchased in 2006-2007. Preliminary observations indicate that the range of labeled levels for adult MVMs has increased. This information will be used as part of the overall evaluation to determine statistically which of the purchased products will move forward for analysis. The DSID project is supported by the Office of Dietary Supplements and the U.S. Department of Agriculture.

INTRODUCTION AND OBJECTIVE:

The Nutrient Data Laboratory (NDL), Beltsville Human Nutrition Research Center (BHNRC), Agricultural Research Service (ARS), USDA, has been working with the Office of Dietary Supplements (ODS), National Institutes of Health (NIH) and other federal agencies to develop a DSID to evaluate dietary supplement products. The DSID is funded, in large part, by the ODS. The first study of MVMs (dietary supplements containing 3 or more vitamins) was conducted to estimate the relationship between label values and analytical values for 18 vitamins and minerals. The product of this research, the DSID-2, was released in March 2012, with national estimates for the vitamin and mineral content of adult and children's multivitamin/mineral (MVM) dietary supplements. (***http://dietarysupplementdatabase.usda.nih.gov***)

The second study is focusing on representative adult MVM products for specific nutrients of interest, representing the three market channels (mass market, natural/health, and direct sales). Product distribution for dietary supplements purchased from these channels as proposed was 50% from mass market, 23% from natural/health, 27% from direct sales. Weighting will be applied for market proportions at a later date.

Iodine will be especially emphasized for analysis due to ODS/public health interest. Vitamins A and D, and chromium will be emphasized to obtain nutrient data not available in DSID-2. This study will also will update adult MVM findings released in DSID-2.

PURCHASE RESULTS:

Adult MVM products were purchased and compared to the first adult MVM study products.

1. Preliminary observations indicate that the maximum labeled levels were higher for Adult MVM-2 for all ingredients except Thiamin. The largest increases were observed with Calcium, Phosphorus, Vitamin B-12, Vitamin C, and Vitamin E. **(Table 1)** It was further observed that some label level ranges of the Adult MVM DSID-2 could be lower due to regression analysis rules established in the first study.

2. Observations of regionally and locally shopped products indicate a product distribution of 44.4% mass market, 34.4% natural/health, and 21.1% direct sales. **(Figure 1)** Adjustments to this distribution will be considered to align products with original sampling plan distribution of 50/23/27 respectively.

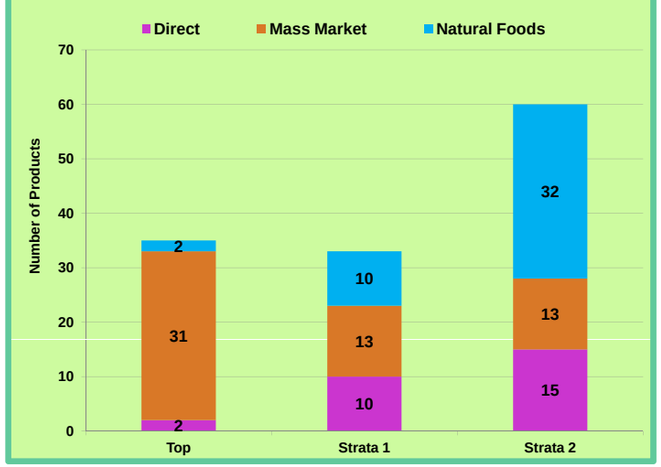
COMPARISON OF ADULT MVM INGREDIENT RANGES FOR 21 INGREDIENTS

Table 1 – Compiled label levels of products in the Adult MVM DSID-2 study (n=115) were compared with products in the Adult MVM-2 study (n=128).

		Adult MVM DSID-2		Adult MVM-2	
DSID Ingredient Name	DSID Unit (per serving)	Minimum Labeled Level in Regression Range	Maximum Labeled Level in Regression Range	Minimum Labeled Level (Observed Range)	Maximum Labeled Level (Observed Range)
Calcium	mg	25	512	10	1220
Copper	mg	0.07	3.5	0.05	3.5
Folic Acid	mcg	50	800	12.5	900
Iodine	mcg	15	150	22.5	225
Iron	mg	0.8	25	0.8	28
Magnesium	mg	10	250	2.5	500
Manganese	mg	0.12	7.5	0.5	10
Niacin	mg	9	150	5	200
Phosphorus	mg	31	130	20	350
Potassium	mg	25	100	1	200
Riboflavin	mg	0.2	100	0.2	125
Selenium	mcg	10	200	1	250
Thiamin	mg	0.2	150	0.2	125
Vitamin B-12	mcg	1	100	1	3000
Vitamin B-6	mg	1	100	0.3	125
Vitamin C	mg	4	1000	4	2000
Vitamin E	IU	9	121	10	400
Zinc	mg	0.401	30	1	42.3

ADULT MVM 2 PRODUCTS BY STRATA AND MARKET CHANNEL (n=128)

Figure 1 – Adult MVM-2 retail products purchased by regional and local shoppers were compiled by strata and market channel to evaluate market distribution.



SAMPLING PLAN:

1. NDL has conducted a national sampling of adult MVMs for two purposes, to:
   - provide nationally representative estimates for nutrients in products commonly reported by the U.S. population (Top Market Share (TMS) products).
   - obtain additional data for lower-market share (LMS) products for the purpose of conducting statistical regression analysis across a range of labeled nutrient levels.

2. NDL developed a multi-stage probability proportional to size (PPS) sampling plans for food and beverages in cooperation with statisticians from the USDA National Agricultural Statistics Service (NASS) (Pehrsson et al., 2000)*. The purpose of the sampling plan is to select sample units from multiple geographic areas of the U.S. that, when analyzed, can provide reliable and representative estimates of means and variability for nutrient content. Similarly, NDL has consulted with statisticians to set up a sampling frame and 3 product-specific plans for the collection of dietary supplement product samples, to assure that samples being analyzed are representative of the market place.

3. Representative products, brands, forms, and market channels for purchase were identified using compiled data from nutrition sales report, market research reports, NHANES, and national shopper surveys.

4. Frequently reported products were identified as top products. After applying an algorithm to assign weighted values, a brand/product list was generated where products for Strata 1 and 2 were identified. (NOTE: Discontinued products were removed.)

5. Finalized list of stores and products organized by market channel. A product list was distributed to contracted shopping vendor. Products identified as mass market or natural/health were purchased by regional shoppers in six locations - AL, NY, CO, CA, MI, MO. Three unique lots were the goal for each product. Direct sales products were purchased by NDL staff from the internet and other direct sales channel sources. Two unique lots were the goal for each product.

6. Each purchased product was recorded by region and lot number. Ingredient, ingredient source, and percent daily value (%DV) for each product were recorded separately.

7. Labeled levels, obtained from product Supplement Facts panels, were compiled to obtain ingredient ranges (per serving levels). **(Table 1)**

NEXT STEPS:

1. A final list of products to be analyzed is being compiled based on a statistical evaluation of market channel breakdown and label levels.
2. Adult MVM-2 products will be analyzed for 21 vitamins and minerals using validated analytical methods at contracted laboratories. Each batch of samples will included one standard reference material (NIST 3280) and two retail in-house controls to monitor accuracy and precision.
3. Statistical regression analysis will be employed to evaluate percent difference from label across a wide range of labeled levels as shown in Table 1.

DEFINITION OF A DIETARY SUPPLEMENT (DSHEA):

The Dietary Supplement Health and Education Act (DSHEA) of 1994, defines a dietary supplement as:

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

***Pehrsson PR, Haytowitz DB, Holden JM, Perry CR, and Beckler DG (2000) USDA's National Food and Nutrient Analysis Program: Food Sampling. J Food Comp Anal. 13:379-389**