New Developments in Federal Databases for Dietary Supplements

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Office of Dietary Supplements & National Cancer Institute, NIH Nutrient Data Laboratory, ARS, USDA CFSAN. FDA, and NHANES, CDC
 Agenda

• Describe critical elements and challenges in developing federal
  • analytically-based dietary supplement databases
  • databases using declarations on labels

• Next steps
Government’s USDA SR for foods, FNDDS

**Why a dietary supplement database?**

- Needed for
  - Federal research (NHANES, etc), other research & policy
  - Identify supplements posing safety concerns
- Congress encourages its creation
Why federal dietary supplement databases?

- **Estimate total nutrient intakes**
  - Total nutrient intakes, gaps, and excesses in US surveys inaccurate if supplements not included (since many people take them)

- **Describe content of non-nutrient bioactives affecting health**
Dietary supplement use shifts the intake distribution curve for folate. Source: NHANES 2001-2002
Composition Databases

- Chemical analysis of ingredients
  - DSID - Dietary supplement ingredient database
- Manufacturer label declarations of chemical analysis
  - NHANES Survey dietary supplement database
  - DSLD pilot Dietary supplement label database
  - NLM National Library of Medicine database
  - FFQ
1. Database of DS ingredients by federal chemical analysis: DSID
• **Goal:** Quantities of ingredients in commonly used categories of products
DSID Critical Elements

• **What it is:** Nutrient estimates based on chemically analyzed values in a federal database

• **Why we need it:**
  • Label declarations do not always reflect amounts in a product
  • Some constituents be risky if exceed UL
DSID
Critical Elements

Sampling plan products from
• national surveys
• and other market sources (multilevel marketers, health practitioners, etc)

Available
• Now
  – Nutrients in Adult MVM supplements
  – MVM Calculator available to compare to label values
• Soon
  – Child MVM supplements
  – Prenatal OTC MVM (in process)
Welcome to the Dietary Supplement Ingredient Database (DSID) home page!

The Nutrient Data Laboratory (NDL), Beltsville Human Nutrition Research Center (BHNRC), part of the USDA Agricultural Research Service, working with the Office of Dietary Supplements, NIH, and other federal agencies, has developed a Dietary Supplement Ingredient Databases (DSID) to estimate levels of ingredients in dietary supplement products.

This first data release of the DSID (DSID-1) provides access to information on analyzed levels of nutrients in adult multivitamin/minerals (MVMs) used in the U.S. These estimates were derived from analytical data generated for a representative set of adult MVM products collected from various U.S. locations.

At this time, the DSID is intended primarily for research applications. For each of eighteen nutrients, product data were grouped by nutrient levels rather than by product names. Statistical regression analyses were used to estimate mean percent differences from label and variability at specific nutrient levels for each of the eight vitamins and ten minerals analyzed. These data are appropriate for conducting population studies of nutrient intake, rather than for assessing individual products.

The main features of DSID include data files, a research summary, and an adult MVM calculator. Regression equations are available for researchers with expertise to calculate multi-nutrient estimates of adult MVM supplement composition. A user-friendly calculator which uses the regression equations is also available as a research tool for those who want to obtain estimates of specific nutrient levels listed on the Supplement Facts labels of a limited number of adult MVMs. These estimates can be saved to build a small database for later use. Since over half of American adults report taking a dietary supplement, the estimates in the DSID will improve assessment of total nutrient intake from foods and supplements.

For more information, you can access DSID research manuscripts and presentations by using the left navigation bar.

DSID Research and Data
- DSID-1 Research Summary
- Data Files & Description

Ingredient Calculator
- Adult MVM Calculator
  - Basic Version
  - Professional Version
- Calculator Instructions
- Calculator FAQs

General Information
- What Is New with DSID?
- Publications & Presentations
- History of DSID
- NDL Web Site
- ODS Web Site
Dietary Supplement Ingredient Database

Adult Multivitamin/mineral Calculator (Basic)

Select Values to Save | Nutrient in DSID (Common Synonyms) | Labeled Amount Per Serving (Valid Range for Prediction) | Predicted Amount for Average Adult MVMs Per Serving | % Difference From Label
--- | --- | --- | --- | ---
Vitamin A (beta-carotene, retinol) | 5000 IU | Expected 2010 | -
Vitamin C | 60 mg (4 - 1000) | 64.6 mg | 7.7
Vitamin D | 400 IU | Expected 2010 | -
Vitamin E (dl-alpha tocopheryl, d-alpha tocopherol) | 30 IU (9 - 234) | 31.8 IU | 5.9
Thiamin (vitamin B-1) | 1.5 mg (0.2 - 1.50) | 1.76 mg | 18
Riboflavin (vitamin B-2) | 1.7 mg (1.2 - 100) | 1.50 mg | 12
DSID Challenges

- **Sampling:**
  - Many prenatals sold by prescription, not OTC
  - Products suspected of lower standards sold in unusual channels are sampled

- **Analysis:**
  - What to do about difficult analyses, as for iodine?
  - High variability in nutrients that do not have a DV and do not have to be declared on the label

- **Prioritization**
• Analytical methods for measuring bioactives in botanicals
• Costly
• Uses
  – Published analyses not product specific; only representative of product composition
• 6 Omega 3 polyunsaturated fatty acids

• Calcium-vitamin D supplements
2. Databases of Label declarations
Label databases

• Nutrient amounts based on *label declarations by manufacturer*
  – Actual amount may be more (overage likely) or less

• May contain
  – Nutrients
  – Other constituents;
    • caffeine, botanicals, chondroitin, etc
  – Other label information
Examples of Label Databases

- NHANES survey dietary supplement label database
- National Library of Medicine label database
- Dietary supplement label database
2a. NHANES Dietary Supplement Label Survey Database:
• **Goal:**
  – Capture nutrients on labels of dietary supplements taken in NHANES

• **Why we need it:**
  – Get total nutrient intakes and to estimate gaps and excesses with FNDDS
### DHES Unified Mineral and Product Supplement Database

#### Listing Of Products by Ingredient

<table>
<thead>
<tr>
<th>Product Id</th>
<th>Product Name</th>
<th>Ingrid Id</th>
<th>Ingridler</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-000-0549-00</td>
<td>GNC LDF PROGRAM VITAPAK SUPPLEMENTS</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
<tr>
<td>1-000-1010-00</td>
<td>GOLDLINE NATURALS GINKGO BILoba EXTRACT</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
<tr>
<td>1-000-0992-00</td>
<td>GOLDLINE NATURALS MEMORY FORMULA</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
<tr>
<td>1-000-0596-00</td>
<td>NATROL GINKGO BILoba EXTRACT, 60 MG</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
<tr>
<td>1-000-0618-00</td>
<td>NATURE MADE GINKGO BILoba 40 MG STANDARDIZED EXTRACT</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
<tr>
<td>1-000-0616-00</td>
<td>NATURE MADE GINKGO BILoba 80 MG STANDARDIZED EXTRACT</td>
<td>10000555</td>
<td>GINKGO BILoba EXTRACT (LEAF)</td>
</tr>
</tbody>
</table>
• Progress to Date:
  – Public use files available since 2003; updated
  – Recent NHANES survey databases included in pilot version of DSLD software pilot
  – Supplements taken by NHANES participants in the past month and past 24 hours to get better estimate of usual intakes
  – Total nutrient intakes now available for NHANES
Challenges
NHANES Dietary Supplement Label Survey Database

- **User friendliness**
  - Files difficult to use and require expertise

- **Limited data**
  - Includes only dietary supplements used in NHANES
  - Quantifies only for nutrients in supplement fact box

- **Timeliness**
  - Must wait 1-2 yr and supplements change

- **Costs**
  - Getting information on dietary supplements is time consuming and logistically difficult.
Next Steps
NHANES Dietary Supplement Label Survey Database

- Develop more user friendly files and software
- Add to other databases
- If a more complete set of supplement labels sold in USA becomes available, use it
ASA-24
Automated self-administered 24-hour Dietary Recall next year will include newest dietary supplements from NHANES.
Goal: Quantities of ingredients declared on labels of virtually all dietary supplements sold in the USA

-focus on research

Sponsors:
Office of Dietary Supplements
National Library of Medicine
• Why we need it
  – Need a database of all dietary supplements sold in USA; none exists at present
  – Much information on label other than that in Supplement Facts box
DSLD Critical Elements

• Progress to date
  – Prototype software “Engine” to group products and system requirements 95% complete
  – Populated with commonly used supplements and two NHANES surveys, including labels
    • Sources sought published June 2010 for small business contractors to populate the database
DSLD Challenges

- Label information only--may not be valid
- Coding:
  - Finding information on the label since locations vary

- Updating

- User needs vary so much information must be captured (consumers, regulators, researchers, industry)
  - Helpful if searchable by brand name, product, nutrient or other ingredient
  - Need software to combine with food intake, etc

- Supplements constantly changing
Dietary supplement database users have varied needs

- **Consumers**
  - “What am I taking, what should I take?”
  - “Is product X different than Y?”

- **Researchers**
  - Total intakes of nutrients in food and DS

- **Industry**
  - Health claims

- **Regulators**
  - Truth in labeling, safety
Many users want more than the supplement facts box.
Next Steps
DSLD

• Adapt a factored food vocabulary (Langual)
  • Increase search capability
  • Better harmonize between
    • Databases for food and dietary supplements
    • Other countries

• Engage contractor to
  Further refine the search engine
  Populate the database with supplement labels
  Periodically update the database
Dietary Supplements Label Database

Federal Business Opportunities

Agency: Department of Health and Human Services
Office: National Institutes of Health
Lead: Office of the Administrator

Solicitation Number: NIHODD0010219
Notice Type: Sources Sought

Synopsis:
This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding (1) the availability and capability of qualified small business sources; (2) whether there are small businesses, HUBZone small businesses, service-disabled, veteran-owned small businesses, small businesses: SBA small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the potential acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is appropriate. An organization that has not previously won a small business under the applicable NAICS code $14000, with a size standard of $7 million, should not submit a response to this notice.

Background:
The Office of Dietary Supplements (ODS), National Institutes of Health, seeks to obtain services related to the data population of a new, web-based application for cataloging all labels of dietary supplements marketed in the USA. From August 2008 through July 2009, the NIH Office of Dietary Supplements (ODS), in cooperation with the National Library of Medicine as specified in a memorandum of agreement, contracted with a private firm to design, develop, and implement a comprehensive
Next Steps

DSLD

• Find ways to encourage vendors to help populate the database
  – keep federal costs of data collection lower by open websites with chemical analyses of products
Next Steps

DSLD

• Take a look at the prototype:
  – Password odsv4

• Let us know your views
Next Steps

- Make software even more user friendly

- Make database available for other federal and non-federal users
  - NCI
    - ASA 24 recall (automated self-administered)
    - Diet & Health Questionaire DHQ (SQFF)
  - Others:
    - Dietary supplement assessment module (DSAM) of U Minnesota
2c. National Library of Medicine
dietary supplement database

Critical Elements

NLM Dietary Supplement Label Database:

- **Goal:** Database of commonly used supplement brand labels, ingredients and references for consumers

- **Why we need it**
  - Permits consumers to compare between products and see product ingredients
Progress to Date

National Library of Medicine NLM
Dietary Supplement Label Database:

• Website up and running

• Links ingredients to PubMed articles

• Permits comparison between two products

• Publicly available
  – Attractive site
  – Updated yearly
Dietary Supplements

Dietary supplements are vitamins, minerals, herbs and other substances meant to improve your diet. They can come as pills, capsules, powders and liquids. Supplements do not have to go through the testing that drugs do.

Some supplements can play an important role in health. For example, pregnant women can take the vitamin folic acid to prevent certain birth defects in their babies. Taking supplements can also be a type of complementary or alternative medicine (CAM).

To take a supplement as safely as possible
- Tell your doctor about any dietary supplements you use
- Do not take a bigger dose than the label recommends
- Stop taking it if you have side effects
- Read trustworthy information about the supplement

Start Here
- Dietary Supplements: Background Information NIH (National Institutes of Health, Office of Dietary Supplements)
- FDA 101. Dietary Supplements (Food and Drug Administration)
- What’s in the Bottle? An Introduction to Dietary Supplements NIH (National Center for Complementary and Alternative Medicine)

Also available in Spanish
Challenges & Next Steps
NLM Dietary Supplement Label Database

• Label collection not a composition database

• Unsuitable for research
  – Cannot manipulate several files
  – Not a downloadable database
  – No software for calculating total nutrient intakes

• Articles not culled - references of variable quality
• Ultimately DSLD will replace the current NLM product and make NHANES supplement data collection easier
What types of Federal dietary supplement databases are available?

- Composition databases
  - Ingredients by analysis
  - Label declarations

- Semiquantitative food frequencies and other software for estimating intakes
  - Dietary supplement databases for food frequency questionnaires
2 d Dietary supplement databases in food frequency questionnaires
Examples of DS Databases in SFFQ

• NCI DHQ ("Block") SQFF (Federal)
  • Updated dietary supplement database live this year or early next (public use)

• Non-Federal but federally supported
  – SURE study FFQ on DS developed by the University of Hawaii (very detailed public use DS questionnaire) free for use with permission suzanne@crch.hawaii.edu
  – Others: may charge
<table>
<thead>
<tr>
<th>VITAMIN TYPE</th>
<th>HOW OFTEN?</th>
<th>FOR HOW MANY YEARS?</th>
</tr>
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<tbody>
<tr>
<td>MULTIPLE VITAMINS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular One-a-Day, Centrum or Thera-type</td>
<td></td>
<td></td>
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<tr>
<td>B-complex or Stress-lab type</td>
<td></td>
<td></td>
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<tr>
<td>SINGLE SUPPLEMENTS</td>
<td></td>
<td></td>
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<tr>
<td>Vitamin C</td>
<td></td>
<td></td>
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<tr>
<td>Vitamin C</td>
<td></td>
<td></td>
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<tr>
<td>Folic acid, folate</td>
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<td></td>
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<tr>
<td>Vitamin B-12</td>
<td></td>
<td></td>
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<tr>
<td>Vitamin B-6</td>
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<tr>
<td>Calcium, alone or combined with something else such as in a bone health supplement OR in an antacid</td>
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<tr>
<td>Vitamin D, alone</td>
<td></td>
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<tr>
<td>Selenium</td>
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<tr>
<td>Iron</td>
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<tr>
<td>Zinc</td>
<td></td>
<td></td>
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<tr>
<td>[Omega-3 fatty acids] Flaxseed</td>
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<tr>
<td>Garlic, as a pill, tablet, or capsule</td>
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<tr>
<td>Glucosamine, alone or combined with something else</td>
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<tr>
<td>Coenzyme Q-10</td>
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<td></td>
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<tr>
<td>Saw Palmetto</td>
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</tr>
</tbody>
</table>

IF YOU TOOK VITAMIN C OR VITAMIN E:

When you took VITAMIN C, how much did you usually take?
- 250 mg or less
- 300 to 500 mg
- 600 to 1000 mg
- More than 1000 mg

When you took VITAMIN E, how much did you usually take?
- 200 IU or less
- 250 to 400 IU
- 450 to 1000 IU
- More than 1000 IU
Progress to Date
DS Databases in semiquantitative food frequency questionnaires

• Permit estimates of total nutrient intake
• Good for research purposes
Challenges
Dietary supplement databases in SFFQ

• Categories and items vary from one FFQ to another
  – Often include categories of supplements rather than brand names
  – Multivitamins, multiminerals, single nutrients

• Amounts often based on a composite or estimate of values for the category

• People don’t know what supplements they take
Next Steps
Dietary supplement databases in SFFQ

• Include more complete dietary supplement databases in federal public use food frequency questionnaires
What's Next?
What’s next??

• Continue to develop analytic databases for high profile ingredients

• Perfect and populate a dietary supplement label database (DSLD) for research

• Add dietary supplements to NCI ASA 24 and DHQ food frequency questionnaires
ODS Dietary Supplement Databases

Components

Intermediate Goals
3-5 yr

Long Range Goals
6-10 yr

DS Labels

- NHANES Survey Label Database
- NLM DS Label Database
- ODS Database of All DS Labels contract

Label Database of all DS Labels (ODS/NLM)

Analytically Validated DS Database (USDA/ODS)

Private Purpose-built DS Databases

Explore collaborations

Combined Database with additional features