Progress in Development of the Dietary Supplement Ingredient Database

Rationale

- Dietary supplement exposure is high: >50%
  - $18 billion/yr
- Public health impact unknown
- Tools to validly document and quantify intakes lacking
Needed to quantify exposure/public health impact of dietary supplements:

- Validated/standardized instruments to collect data
- Composition of dietary supplements
- Validated tools to analyze data
ODS Objective: Quantify intakes of nutrients/bioactive constituents in dietary supplements (DS)

- Enhance database development
  - Validated methods of data collection
  - Validated tools to analyze data
Challenges in setting up a dietary supplement compositional database

1. Categorizing product types in the database

2. Identifying nutrients/components of public health interest in these products

3. Quantifying those nutrients/components
### Challenges: DS Products, Components and Quantities

<table>
<thead>
<tr>
<th>Products</th>
<th>Iron</th>
<th>Daidzein</th>
<th>Omega 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin Mineral</td>
<td>25 mg</td>
<td>100 mcgm</td>
<td>15 mg</td>
</tr>
<tr>
<td>Products for seniors</td>
<td>10 mg</td>
<td>200 mcgm</td>
<td>30 mg</td>
</tr>
<tr>
<td>MVM for children</td>
<td>2 mg</td>
<td>2 mcgm</td>
<td>2 mg</td>
</tr>
</tbody>
</table>
Challenge #1

Categorizing products in the database
Categorizing Products: Best ways to categorize products depends on purpose—one logical grouping

<table>
<thead>
<tr>
<th>Products</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Grain &amp; grain products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cereal</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Foods: Conventions accepted for categories

- Source/origin

- Use in meals

- Nutrients
  - rich sources of nutrients
Drug category conventions also exist

- Intended or end use or function:
- Chemical names
DS: Conventions not yet identified
Many schemes possible

- Origin
- Brand/manufacturer
- End use
- Chemical content
- Market share
## Categorizing Products: DS Database

<table>
<thead>
<tr>
<th>Products</th>
<th>One logical grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin Mineral Products</td>
<td></td>
</tr>
<tr>
<td>MVM for seniors</td>
<td></td>
</tr>
<tr>
<td>MVM for children</td>
<td></td>
</tr>
</tbody>
</table>
Problems: DS Categorization

**Today:** Myriad classifications used
- Logic unclear
- Categorization of convenience common
- Decisions subjective rather than objective

**Implications**
- Makes comparison between studies difficult
- Variability of nutrients within categories often great
- Categories often not mutually exclusive
Principles: Categorization of DS

- Identify & standardize useful classification schemes for various uses
- Explicit rationale/ logic & categorization criteria
- Homogeneity
- Mutually exclusive categories
Challenge #2

Identify nutrients/components of public health interest to put into the database
Identify Nutrients/Bioactive Components: DS Database

<table>
<thead>
<tr>
<th></th>
<th>Iron</th>
<th>Daidzein</th>
<th>Omega 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mineral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVM for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>seniors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MVM for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>children</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16 DSID
Challenge 2: Identify and prioritize nutrients/components of greatest public health interest

- Need list of nutrients/components of importance
  - Dietary supplements contain several nutrients/components
  - Interest is only on some of these
- Select most critical components – priority ranking
Basis for deciding on critical components

- Frequency of consumption (NHANES)
- Public health significance (DRI nutrients so of known benefit, nutrient known to be short in diets etc)
- Availability of methods and reference materials
- Federal agency interest
Dietary Supplement Ingredient Database
Priority List:

**Phase 1**
- Calcium, iron, magnesium, selenium, zinc
- Folate Vitamins A, B-carotene B6, B12, C, D, E
- Omega-3 fatty acids
- Potassium
- Sodium
- Iodine

**Phase 2**
- B vitamins (B1, B2, niacin, pantothenic acid, biotin)
- Vitamin K
- Copper, chromium, manganese, molybdenum
- Phosphorus
- Lycopene, lutein, Ginkgo, isoflavones
- Caffeine
Challenge #3

Quantifying priority nutrients/components
**Big Problem for Dietary Supplements**

- Few publicly available chemically analyzed values for DS
- Only values declared on label available
<table>
<thead>
<tr>
<th>Products</th>
<th>Iron</th>
<th>Daidzein</th>
<th>Omega 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamin Mineral Products</td>
<td>25 mg</td>
<td>100 mcgm</td>
<td>15 mg</td>
</tr>
<tr>
<td>MVM for seniors</td>
<td>10 mg</td>
<td>200 mcgm</td>
<td>30 mg</td>
</tr>
<tr>
<td>MVM for children</td>
<td>2 mg</td>
<td>2 mcgm</td>
<td>2 mg</td>
</tr>
</tbody>
</table>
Challenge #3: Quantify priority nutrients/components

- **Nutrients: straightforward:**
  - Active components known
  - Also in foods
  - Analytical methods often known
    - although matrix varies, method can be validated
  - Benefits & public health importance known
Saw Palmetto
Challenge #3: Quantify priority nutrients/components

- Botanicals: problematic
  - Active component largely unknown
  - Analytical methods not developed
  - Form not necessarily same as in foods
  - Efficacy often not established
  - Public health relevance unknown
Ginkgo biloba
Challenge #3: Issues in quantifying priority nutrients/components

- Availability of analytical methods
- Availability of reference materials
- Necessary level of accuracy
- Developing appropriate sampling plans.
Availability of reference materials

Problem:
- Reference standards lacking to standardize chemical analysis of dietary supplements

Steps toward a Solution:
- Develop standard reference materials (SRM) or certified reference materials (CRM) for dietary supplements that labs can use
Standard Reference Materials (SRM)

- Cooperative agreement with National Institute of Standards and Technology (NIST) to prepare SRM
  - Multivitamin-mineral supplement
  - Ephedra, ginkgo, saw palmetto, St John’s wort, bitter orange, green tea, beta carotene, alpha tocopherol
  - Also NIST will update cod liver oil SRM to show individual fatty acids
St. John’s wort
Needed analytical accuracy

- Certain vitamins, minerals and other nutrients need high accuracy
  - Why: high public health import
    ~ Ex folic acid, calcium, D
    ~ Need estimates of total dietary intake

- Botanicals: depends on substance
Developing appropriate sampling plans

- Demographic sampling frame

- Marketing sectors for products defined to begin process
DS Marketing Sectors

- Grocers
- Druggists
- Direct marketing
- Alternative medical practitioners
- Natural/health stores
- VMS supplement stores
- Clubs
Proposed ODS/ARS/USDA Pilot to test current labs ability to analyze VMS commonly consumed in NHANES 99-2000

- 1. Methods for foods ok for DS?
- 2. Do labels reflect actual contents of the DS?
- 3. Variability between lots?
Putting pieces of the pieces of the puzzle together

A practical example
A practical problem: What we are up against in estimating total dietary intakes?

- Example: Does calcium intake affect blood pressure?
  - If yes, what is
    - contribution of food sources,
    - supplements
    - antacids
Challenges

- **Food sources**
  - calcium fortified sources difficult to identify

- **Antacid use**
  - Collected in NHANES, may not be in other surveys

- **Supplement use**
  - Collected in NHANES, but past 30 days and only label values reported by manufacturer available

- **Total dietary intake of calcium**
  - *May be very inexact, especially in older age groups that take lots of fortified foods and supplements!*
Challenge: supplemental sources of calcium

- Only label values provided by the manufacturer are available in database
  - Accuracy of these values not published
  - No analytic values available in public domain on these items

- Large number of products

- Products constantly changing
Solution

- Collect and analyze for food sources
  +
- Collect and merge data on antacid use
  +
- Collect and merge data on supplement use

Total dietary intake of calcium
Progress toward analytically supported Dietary Supplement Data Base

Goal: Analytically supported Dietary Supplement Database

NHANES label-based Dietary Supplement Database

DSID Dietary Supplement ingredient database at ARS
We are here

PROVIDE SAMPLES to labs

DRAFT & ISSUE RFP

TELL STAKEHOLDERS

IDENTIFY methods -labs -pilot

DEVELOP CRITERIA -methods -labs

Process
Visit the ODS home page

http://ods.od.nih.gov
Give us your views!