Progress in Developing Dietary Supplement Databases at NIH’s Office of Dietary Supplements

Dietary Supplement Ingredient Database (DSID) and Label Databases (DSLD)

Agenda

- Analytically validated database
  - Dietary supplement ingredient database (DSID)

- Label databases
  - NHANES dietary supplement label database (NHANES-DSDL)
  - Dietary supplement label database of all dietary supplements marketed in USA (DSLD-USA)

- Related activities
Rationale

- Dietary supplement exposure high: >50%
  - Public health impact unknown
  - Lack tools to quantify intakes
Focus Today

Quantifying nutrients/bioactives in DS

Analytical values needed
Dietary Supplement Ingredient Database (DSID)

- **What it is**
  - Database for key DS ingredients of public health importance supported by chemical analysis

- **Why we need it**
  - In USA, mandatory certification or registration of DS ingredients not required
  - Only label declarations are available
Challenge #1

Selecting components for the database
Priorities were mostly nutrients:

- Calcium, iron, magnesium, selenium, zinc
- Folate Vitamins A, B-carotene, B6, B12, C, D, E
- Omega-3
- Potassium
- Sodium
- Iodine
- B vitamins (B1, B2, niacin, pantothenic acid, biotin)
- Vitamin K
- Copper, chromium, manganese, molybdenum
- Phosphorus
- Lycopene, lutein, Ginkgo, isoflavones
- Caffeine
Why MVM?

- High prevalence
- Few chemically determined values available
  - Only label declarations usually provided
- Most store brands fairly consistent and at DV levels but MVM in multilevel marketing vary widely in % DV
- Consumers and researchers may not be getting what they think
USDA Projects

IDENTIFY
-best methods for DS
-labs
-pilot

DEVELOP
CRITERIA
-methods
-labs

PROVIDE SAMPLES
to labs

SAMPLE MVM
Nationally & Perform Analyses

CONTRACT
For Labs

ARS Is here
Existing methods may not be qualitatively or quantitatively accurate and economically reasonable for DS

- Robust or adequate methods
  - most minerals
  - most water soluble vitamins except B12
  - some fat soluble vitamins $\alpha$ tocopherol and K

- Adequate but limited:
  - some B vitamins because methods not generally agreed upon
  - high variability for D, retinol and $\beta$ carotene
Standard Methods for Dietary Supplements

• Problem
  ‣ DS matrices, excipients and other factors differ from foods
  ‣ Chemical methods developed for foods may not work for DS

• Solution:
  ‣ Work with AOAC (Association of Analytical Chemists International) to improve methods via ODS Analytical Methods and Reference Materials Program
Standard Reference Materials

Problem

- Standard reference materials for calibrating chemical analyses often do not exist for DS

Solution:

- Work with NIST (National Institute of Standards & Technology) to develop reference materials
Availability of analytical methods.

- Many ingredients, but little time and money
  - ODS / government can only show the way to go
  - Others must finish the job

- For some dietary supplements, active constituents unknown
AOAC Methods in Development

NIST Standard Reference Materials in Development
Gingko biloba
Quantifying priority components

- **Botanicals:** problematic
  - Active component
    - Often unknown
    - Form may be different
  - Analytical methods often not developed
  - Public health relevance unknown
    - Perceived, not necessarily demonstrable benefits
    - Adverse effects also possible
Improving Dietary Supplement Label Databases (DSLD)

- **What they are**
  - Label databases for DS ingredients of public health importance
  - NHANES DSLD
    - for DS reported in NHANES surveys
  - DSLD-USA *(concept stage)*
    - For all DS marketed in the USA

- **Why we need them**
  - Analytically verified databases not available
  - Dietary intakes incomplete if DS not included
  - Need to connect DS exposures and health
Dietary Supplement Label Databases (DSLD): Why two??

- **NHANES DSLD**
  - Covers only a small portion of entire DS products available
  - Products change rapidly and NHANES released in 2 yr cycles about 2 yr after collection
  - Database chiefly for research use

- **DSLD-USA**
  - Will be more complete
NHANES DSLD

- Publicly available
  - http://www.cdc.gov/nchs/about/major/nhanes/NHANES99.00.htm

- Training
  - NHANES Online Analyst for DS (NOADS):
    - web based tool for analysis of total nutrient intakes and their relationship to biomarkers of nutritional status: prototype folate and B-12
  
  - July 2008 NCHS Data users session, Washington
DSLĐ-USA (all DS marketed in USA)  
...._in concept stage_

- **What it is**
  - Web based publicly available listing virtually all DS marketed in USA

- **What it will do**
  - Provides a central source of supplement labels
  - Label information from streams other than usual retail sales
Supplement Marketplace

30,000 to 50,000 products

Raw Materials
- 200 suppliers
- 1000+ growers & handlers, refiners, extractors

Manufacturers And Processors
- 890 companies

Retail Sales
- 13K natural/health stores
- 8K VMS suppl/GNC
- 101K grocers
- 42K druggists
- 6K clubs
- 65K convenience

Direct Sales
- 1K direct marketing
- 451K alternative medical practitioners
Desirable features DSLD-USA

- User-friendly web interface

- Information accuracy and quality
  - Digital image of product label
  - Automatic processes verification accuracy of label information
  - Unique identifiers - structured product labeling
  - Structured vocabularies and dictionary of synonyms

- Update and archive periodically
Challenges

- What should a publicly available DS database “look” like???

- What is
  - Most useful kind of information on DS to collect in federal surveys like NHANES
  - Best ways to collect it
Related Activities

- Studies of motivations for DS use
  - Natural Marketing Institute
  - National Health Information Survey supplement on complementary and alternative medicine in 2007
  - NHANES limited questions on DS use in pilot
Related Activities

- Grant support:
  - DS software U Minnesota
  - Methods U Hawaii Cancer Center

- State of the Science Conference on MVM and Chronic Disease Risk in Adults
SOS on MVM and Chronic Disease Risk in Adults

- Evidence based review

- Outside expert panel report
  - http://consensus.nih.gov/2006/MVMFINAL05

- AJCN supplement forthcoming
MVM Panel Report

- Actual amounts of total nutrients Americans consume from diet and DS not clear
- Need improved methods for obtaining accurate current data on intakes, including MVM databases with exact composition of DS
- Few rigorous studies of MVM efficacy; more RCT needed for efficacy and safety
MVM Panel Report

- Present evidence insufficient to recommend either for or against use of MVM by public to prevent chronic disease

- More research and better communication between scientists, health care providers, patients industry, consumers and public needed
Conclusion: Better dietary supplement databases remain a priority

- Interest in health benefits of DS high

- Concern about excess or deficient amounts of nutrients and exposure to other bioactives continues
We are making progress toward better DS Databases

Goal: Analytically supported Dietary Supplement Databases

NHANES DS LD & DSLD-USA label-based Dietary Supplement Database

DSID Dietary Supplement ingredient database at ARS
Cross-cabinet level collaboration makes it all possible!!!!!!!!