

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

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

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Agenda

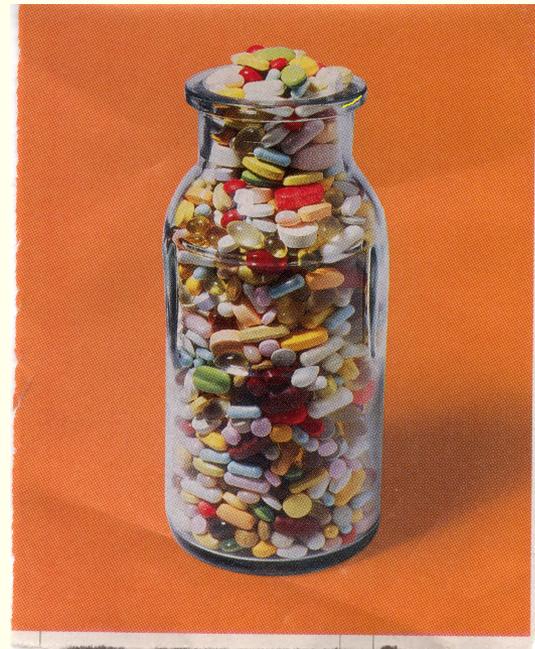
- **Analytically validated database**
 - ▶ **Dietary supplement ingredient database (DSID)**

- **Label databases**
 - ▶ **NHANES dietary supplement label database (NHANES-DSLID)**
 - ▶ **Dietary supplement label database of all dietary supplements marketed in USA (DSLID-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



Dietary Supplement Ingredient Database

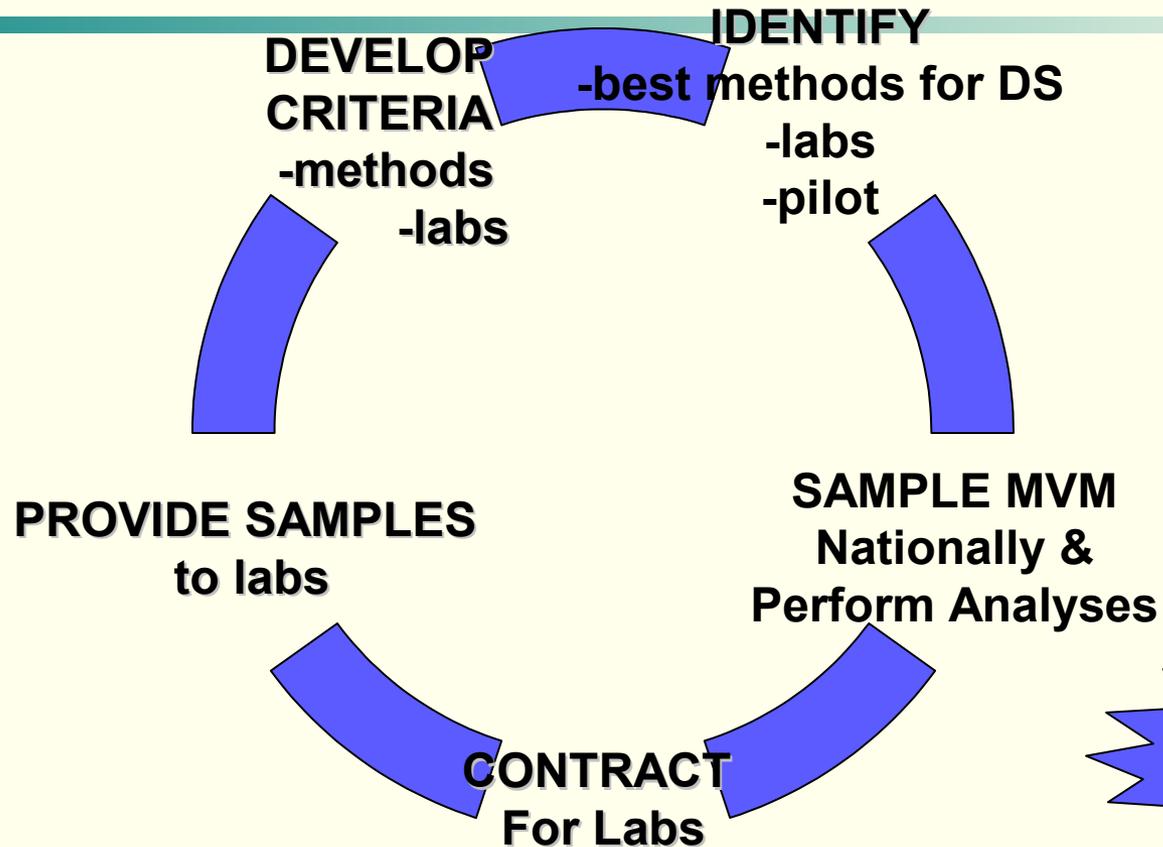
Priorities were mostly nutrients:

- 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



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 α tocopherol and K

- **Adequate but limited:**

- ▶ some B vitamins because methods not generally agreed upon
- ▶ high variability for D, retinol and β 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:**

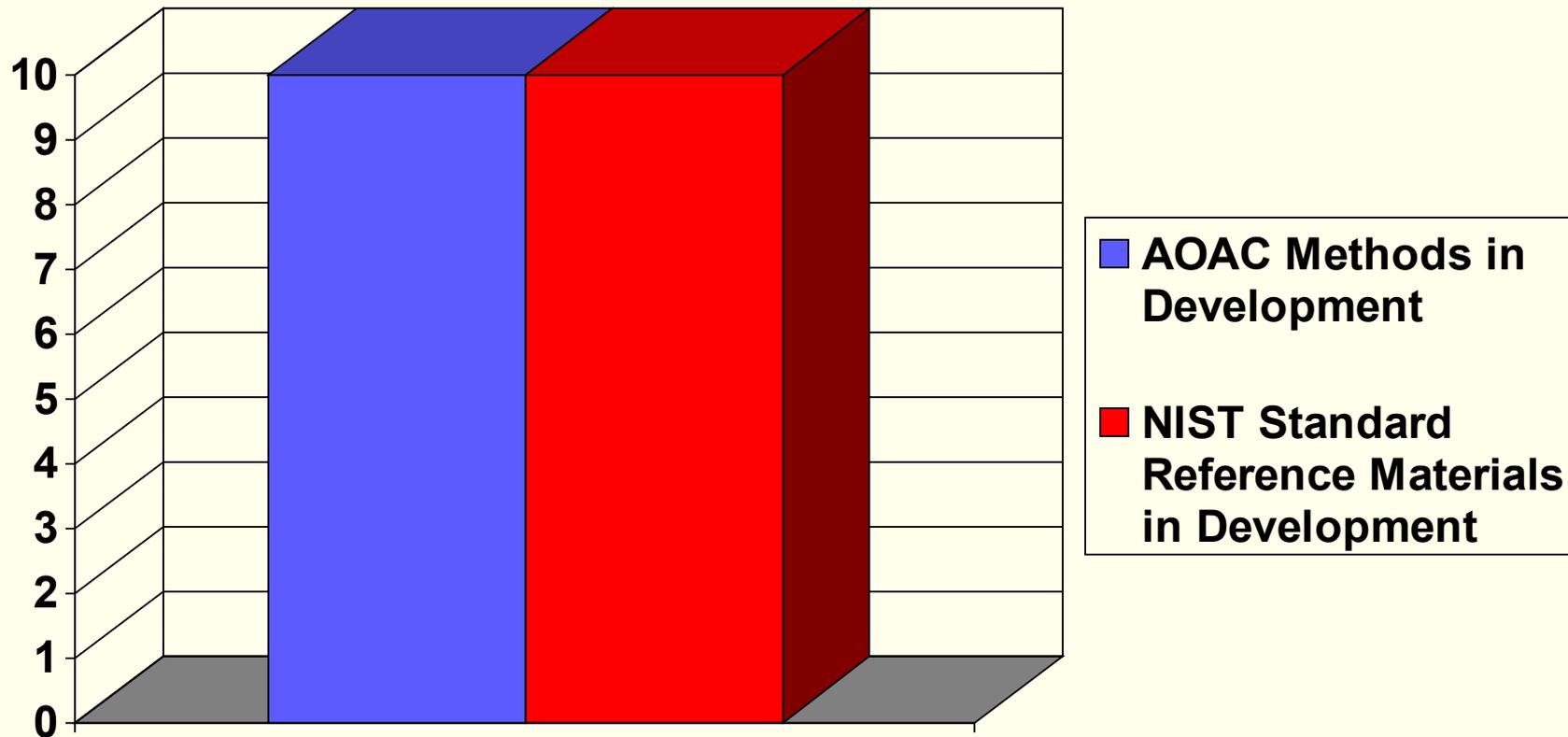
- ▶ **Work with NIST (National Institute of Standards & Technology) to develop reference materials**

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**

Under Development



Ginkgo 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 (DSLDD)

▪ What they are

- ▶ Label databases for DS ingredients of public health importance
- ▶ NHANES DSLDD
 - ~ for DS reported in NHANES surveys
- ▶ DSLDD-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 (DSLSD): Why two??

- **NHANES DSLSD**

- ▶ 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

- **DSLSD-USA**

- ▶ Will be more complete

NHANES DSLD

- Publicly available
 - ▶ <http://www.cdc.gov/nchs/about/major/nhanes/NHAN>
- 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

DSLID-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
- 8 K VMS suppl/GNC
- 101 K grocers
- 42 K druggists
- 6 K clubs
- 65 K convenience

Direct Sales

- 1 K direct marketing
- 451 K 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
 - ~ www.ahrq.gov/downloads/pub/br>evidence/pf/multivit.pdf
- 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

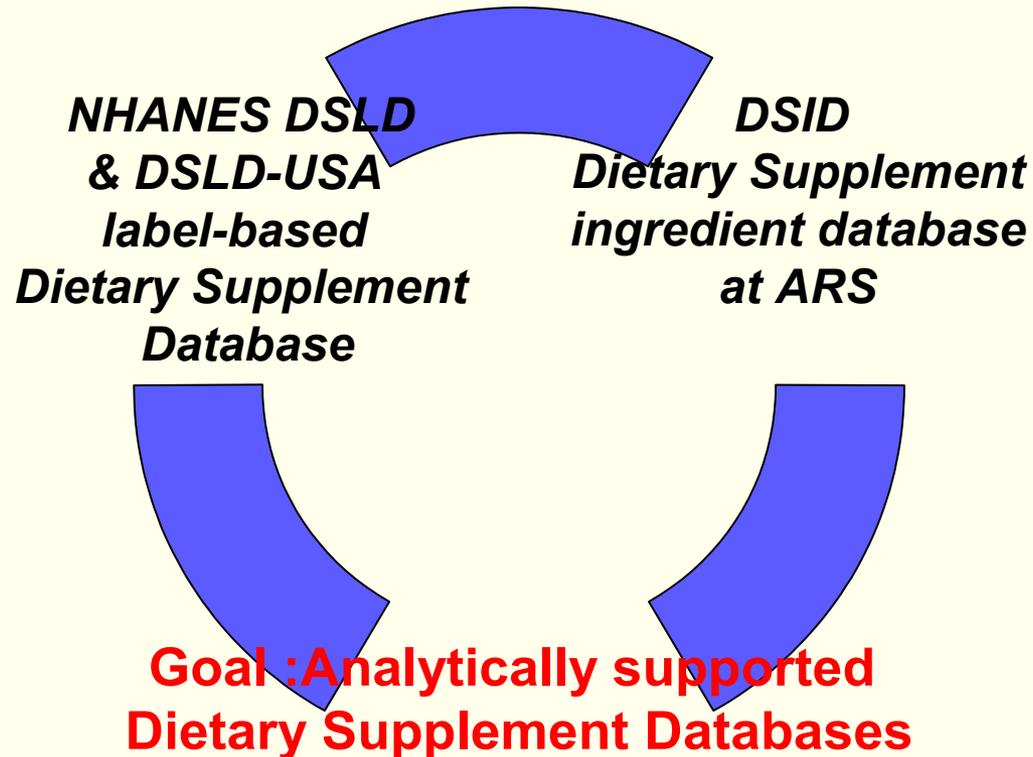
MVM Panel Report

- 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



Cross-cabinet level collaboration
makes it all possible!!!!!!!



Dietary Supplement Ingredient Database