The Essential Balance:
Risks and Benefits in Food Quality and Safety Assessments

Barbara Burlingame, PhD
Outline

1. Composition of foods
2. The continuum
3. Diet related risks and benefits
4. Harmonization issues
5. Recommendations
What is a nutrient?

Historic: Components of food that cannot be made by the body, but are required for normal growth and development; the lack of which causes organ system or cell dysfunction that can be reversed upon reintroduction into the diet.
What is a nutrient?

"It is a fully characterized (physical, chemical, physiological) constituent of a diet, natural or designed, that serves as a significant energy yielding substrate, or a precursor for the synthesis of macromolecules or of other components needed for normal cell differentiation, growth, renewal, repair, defence and/or maintenance or a required signaling molecule, cofactor or determinant of normal molecular structure/function and/or a promoter of cell and organ integrity."

Furthermore…

“…the definition does not allude to the concept of nutrient essentiality,” and

“…can be harmful”

What is a nutrient?

1. Defining the Food-Drug Continuum
   - Food-Drug-Toxicant Continuum
2. Lutein, lycopene, ß-cryptoxanthin
3. Phytate, oxalates, tannins
4. Caffeine, salicylates
Disease

- Communicable
- Non-communicable

Malnutrition

- Undernutrition
- Overnutrition
AGRICULTURE & HEALTH

Evidence
1. Convincing
2. Probable
3. Possible
4. Insufficient
Summary of evidence, part 1

<table>
<thead>
<tr>
<th>Energy and fats</th>
<th>CVD</th>
<th>Obesity</th>
<th>Type 2 diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>High intake of energy-dense foods</td>
<td></td>
<td>C↑</td>
<td>Po↑</td>
</tr>
<tr>
<td>Saturated fatty acids</td>
<td>C↑</td>
<td></td>
<td>P↑</td>
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<tr>
<td>Trans fatty acids</td>
<td>C↑</td>
<td></td>
<td>Po↑</td>
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<tr>
<td>Dietary cholesterol</td>
<td>P↑</td>
<td></td>
<td></td>
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<tr>
<td>Myristic and palmitic acid</td>
<td>C↑</td>
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<tr>
<td>Linoleic acid</td>
<td>C↓</td>
<td></td>
<td></td>
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<tr>
<td>Fish and fish oils (EPA and DHA)</td>
<td>C↓</td>
<td></td>
<td>Po↓</td>
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<tr>
<td>Plant sterols and stanols</td>
<td>P↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>α-Linolenic acid</td>
<td>P↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oleic acid</td>
<td>P↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stearic acid</td>
<td>P-NR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuts (unsalted)</td>
<td>P↓</td>
<td></td>
<td></td>
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</tbody>
</table>
# Summary of evidence, part 3

<table>
<thead>
<tr>
<th></th>
<th>CVD</th>
<th>Cancer</th>
<th>Dental disease</th>
<th>Osteoporosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vitamins</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Vitamin C deficiency</td>
<td></td>
<td></td>
<td></td>
<td>C↑</td>
</tr>
<tr>
<td>Vitamin D</td>
<td></td>
<td></td>
<td>C↓</td>
<td>C↓</td>
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<tr>
<td>Vitamin E supplements</td>
<td>C-NR</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Folate</td>
<td></td>
<td>P↓</td>
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<tr>
<td><strong>Minerals</strong></td>
<td></td>
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<td></td>
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<tr>
<td>High sodium intake</td>
<td></td>
<td></td>
<td>C↑</td>
<td></td>
</tr>
<tr>
<td>Salt-preserved foods and salt</td>
<td></td>
<td></td>
<td>P↑</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td></td>
<td>C↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
<td></td>
<td>C↓</td>
</tr>
<tr>
<td>Fluoride, local</td>
<td></td>
<td></td>
<td></td>
<td>C↓</td>
</tr>
<tr>
<td>Fluoride, systemic</td>
<td>C↓</td>
<td></td>
<td>P-NR</td>
<td></td>
</tr>
<tr>
<td>Fluoride, excess</td>
<td></td>
<td></td>
<td>C↑</td>
<td></td>
</tr>
<tr>
<td>Hypocalcaemia</td>
<td></td>
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<td>P↑</td>
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</tbody>
</table>
Food composition data form the basis by which intakes, and hence diet-disease relationships, are assessed.

Food composition data are the fundamental information by which dietary intake goals can be established and achieved.

Without sufficient quantity and quality of compositional data—past, present and future—all diet/disease evidence would be insufficient.

The body of data can and should be worldwide.
A Model for Establishing Upper Levels of Intake for Nutrients & Related Substances

• Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment

• 2-6 May 2005

http://www.who.int/ipcs/highlights/full_report.pdf
<table>
<thead>
<tr>
<th>EFSA-SCF&lt;sup&gt;a&lt;/sup&gt;</th>
<th>EVM&lt;sup&gt;b&lt;/sup&gt;</th>
<th>IOM&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review upper levels of daily intakes of individual vitamins and minerals that are unlikely to pose a risk of adverse health effects;</td>
<td>Establish principles on which to base controls for ensuring the safety of vitamin and mineral supplements sold under food law;</td>
<td>Develop a model to establish the maximum level of a nutrient intake that would pose a low risk of adverse effects. Apply the model to [the substances in question] to develop Tolerable Upper Intake Levels.</td>
</tr>
<tr>
<td>Provide a basis for the establishment of safety factors, where necessary, for individual vitamins and minerals to ensure the safety of fortified foods and food supplements containing these nutrients.</td>
<td>Review the levels of individual vitamins and minerals associated with adverse effects;</td>
<td></td>
</tr>
<tr>
<td>Recommend maximum levels of intake of vitamins and minerals from supplements if appropriate; report to the Food Advisory Committee.</td>
<td>Advise on the levels of vitamins and minerals in fortified foods, when appropriate.</td>
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<tr>
<td>n.b., EVM preferred to frame advice in terms of additional intake, covering both supplements and fortified foods, rather than as separate categories.</td>
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</tbody>
</table>

<sup>a</sup> EFSA-SCF: European Food Safety Authority Scientific Committee on Food

<sup>b</sup> EVM: Established Upper Levels of Mineral Intake

<sup>c</sup> IOM: Institute of Medicine
The consultation

1. Recognise the continuum
2. Develop a process
3. Use the risk assessment framework
4. Estimating the distribution of usual nutrient exposures in populations
   - Food, water, supplements
   - Form of the nutrient
   - Population subgroup
   - Time frame
Risk Assessment

- Foster interactions between risk managers and risk assessors to ensure common understanding of the problem and to refine problem formulation as needed.

- Define data search strategy a priori.
- Identify adverse health effects and related levels of intake.
- Rate and summarize data objectively.
- Determine basis for selection of the critical adverse health effect.
- Clarify intake–response relationship to identify benchmark intake (BI), no observed adverse effect level (NOAEL), or lowest observed adverse effect level (LOAEL).
- Adjust the BI, NOAEL, or LOAEL for uncertainty, and establish upper level of intake (UL).
- As necessary, adjust UL derived for a studied subpopulation to derive ULs for unstudied age/sex/lifestage subpopulations.

- Specify need for total dietary intake or targeted dietary intake data.
- Specify need for habitual intake or acute intake data.
- Modify or add to available composition data as needed.
- Take into account strengths and limitations of available consumption data.
- Determine method to estimate intake of nutrient substance.
- Make statistical adjustments to estimated intakes as appropriate.
- Provide caveats for estimates based on uncertainties, and describe the impact of uncertainties.

- Integrate hazard characterization and dietary intake assessment.
- Identify types of information needed by managers and the presentation format.
- Include relevant descriptions of: the nature of the critical adverse health effect and other effects as appropriate, severity and reversibility of effects, and nature of threshold levels and dose–response relationship.
- Describe the impact of uncertainty on conclusions.
Dietary assessment = Exposure assessment

- **Survey instrument**
  - Usual intakes or acute intake data
  - Existing survey or new survey

- **Food database**
  - Foods, supplements, water
  - Nutrients, bioactive non-nutrients, contaminants
  - Existing data or new data
  - Data ranges
<table>
<thead>
<tr>
<th><strong>Objective</strong></th>
<th><strong>Dietary assessment</strong></th>
<th><strong>Exposure assessment to chemicals</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Assess dietary pattern and food / nutrient adequacy</td>
<td>Assess exposure to substances with a potential health risk</td>
</tr>
<tr>
<td><strong>Comparison with reference data</strong></td>
<td>Nutrient requirement (depending on weight, height, sex, age, physiological status, physical activity)</td>
<td>No-observed-effect level (NOEL), No-adverse-effect level (NOAEL), ADI (60 kg body weight)</td>
</tr>
</tbody>
</table>
| **Data used** | - Food consumption/supply data  
- Nutrient composition of foods (from food composition databases) | - Food consumption/supply data  
- Concentration data (rarely in national FCDB)  
- Total diet study |
| **Types**     | - Rough estimation, food supply data  
- Detailed assessment | - Screening / rough estimation  
- Detailed assessment |
| **Statistical unit** | Household or individual (type 1)  
National or international (type 2) | Individual  
National or international |
| **Main sources of errors** | - Design of food consumption study  
- Supplements inclusion  
- Adequacy and quality of FCDB  
- Respondent and interviewer bias  
- Treatment of missing data | - Sampling and prep of foods analysed  
- LOQ, treatment of data (< LOQ)  
- Adequacy and quality of food consumption and concentration data  
- Exposure assessment methodology |
Harmonisation Issues

- Nutrient definitions
- Methods of analysis
- Forms (vitamers, elemental speciation)
- Modes of expression
- Energy factors
- Bioavailability
- Labelling
- Requirements, MRLs, ULs
- The chemist vs technologist vs policy-maker vs the consumer
A major goal of INFOODS...

The development standards for compiling and interchanging food composition data:

- Nomenclature, terminology, descriptor systems
- Component identification
- International interchange
The essential balance: risks and benefits in food safety and quality

- Risks and benefits
  - Nutrients and antinutrients
  - Chronic disease risk and prevention
  - Functional additives
- Food safety, chemical contaminants
- Authentication & validation
- New methodological approaches
- Quality parameters, beyond conventional nutrients
Food composition and dietary intakes

1. Foods are nutrients, toxicants, contaminants, and more;
2. Nutrients can be contaminants and toxicants;
3. A dietary assessment is a risk assessment;
4. Nutrient intakes are exposures;
5. A food composition database should be an additive database, a contaminant database, toxicant database and a nutrient database.
Conclusions/Recommendations

1. Collect more and better food consumption data at individual level;
2. include all ingestants: water, supplements, etc.;
3. generate and compile high quality compositional data (nutrient and contaminants) using standards;
4. increase collaboration between food safety and nutrition;
5. multiple goals: assessing nutrient adequacy, better understanding risk, establishing nutrient requirements, UL, MRL;
6. share the data.
Grazie

Thank you