Dietary Supplement Use in the United States
Maria Thurston, PharmD, BCPS

Live Activity Handout
4 slides per page
Dietary Supplement Use in the United States

**ACTIVITY DESCRIPTION**
Dietary supplements are commonly used by patients nationwide and sold in almost every community pharmacy today. In fact, one in 10 people use 5 or more dietary supplements daily. Dietary reference intakes have been established for key vitamins and nutrients, but supplements are actually regulated as foods by the Office of Dietary Supplements (ODS). Commonly used supplements include: multi-vitamins, calcium, fish oil, and vitamin D, to name a few. Unfortunately, there have been recent scandals involving the safety and efficacy of dietary supplements in the United States. Therefore, it is imperative that clinicians have the knowledge, skills, and resources necessary to provide recommendations and education regarding their appropriate use and safety concerns.

**TARGET AUDIENCE**
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

**LEARNING OBJECTIVES**
After completing this activity, the pharmacist will be able to:
- Review what constitutes a dietary supplement
- Describe key regulations associated with dietary supplements
- Evaluate the safety and efficacy of dietary supplement use
- Identify reputable dietary supplement resources to enhance practice and provide patient education

After completing this activity, the pharmacy technician will be able to:
- Review what constitutes a dietary supplement
- Identify common dietary supplements and their uses

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Knowledge-Based Live Webinar

**FINANCIAL SUPPORT BY**
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ABOUT THE AUTHOR
Dr. Maria Thurston graduated with honors from the University of Georgia College of Pharmacy. She completed a PGY-1 pharmacy practice residency with the Atlanta Veterans Affairs Medical Center in Decatur, Georgia and a PGY-2 ambulatory care residency specializing in academia with the University of Georgia/Charlie Norwood Veterans Affairs Medical Center, where she also obtained a Graduate Certificate in Clinical Pharmacy. Dr. Thurston’s areas of interest and expertise include: cardiovascular risk reduction, health coaching, patient education, interprofessional education and professional development. Dr. Thurston achieved the designation of Board Certified Pharmacotherapy Specialist in 2011. She was named the Georgia Society of Health-System Pharmacists Outstanding Young Health-System Pharmacist in 2012 and received the American College of Clinical Pharmacy Ambulatory Care PRN Member Recognition Award in 2016. She is currently serving as a Clinical Assistant Professor in the Department of Pharmacy Practice with Mercer University College of Pharmacy where she coordinates the Nervous Systems Disorders II course and teaches various didactic lectures. She actively practices in a collaborative internal medicine clinic affiliated with Wellstar Atlanta Medical Center, where she precepts both pharmacy students and residents. She serves on committees for multiple regional and national pharmacy organizations and is a peer reviewer for scholarly journals. Her numerous regional and peer-reviewed publications are focused on topics relevant to primary care practice, and she has research and grants in the areas of medication adherence, health literacy, diabetes, heart failure, hypertension, mobile apps, interprofessional education, and professional development.

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Learning Objectives

1. Review what constitutes a dietary supplement
2. Describe key regulations associated with dietary supplements
3. Evaluate the safety and efficacy of dietary supplement use
4. Identify reputable dietary supplement resources to enhance practice and provide patient education

Background of Dietary Supplements

- Prevalence of regular supplement use
  - 48%-53% from 2007 to 2011
- Significant increase in those who "regularly used a variety of supplements"
  - 28% → 36% from 2010 to 2011
- Supplement use
  - Increases with age
  - Higher in women than in men

- 2011: 67% of respondents used vitamin or mineral supplements
  - Multivitamins were the most commonly used supplement (71%)
  - Omega-3/fish oil (33%), calcium (32%), vitamin D (32%), vitamin C (32%)
- Reasons most often cited for supplement use
  - Overall health and wellness (58%)
  - To fill nutrient gaps in the diet (42%)
- Data indicate supplement use is "part of an overall approach to living healthy"

Dietary Supplements in the News!

- Calls to poison control centers in the U.S. due to exposures to dietary supplements rose nearly 50 percent between 2005-2012
  - 70% involved children 6 years old and under

- Report published in the Journal of Medical Toxicology
  - Called for an increase in regulation by the Food and Drug Administration (FDA) for certain supplements that were associated with high amounts of toxicity

Dietary Supplement Definition

- Defined by the Dietary Supplement Health and Education Act (DSHEA) of 1994

  - A product, other than tobacco, that:
    - Supplements the diet
    - Contains one or more dietary ingredients
    - Intended to be taken by mouth
    - Labeled as dietary supplement

New Dietary Ingredient

- Not sold in U.S. in dietary supplement before October 15, 1994

- FDA requires specific safety information
  - Ingredients present in food supply
  - History of use or safety evidence

- Dietary ingredient as defined by DSHEA

Rules and Regulations

- DSHEA 1994
  - Regulated by FDA as foods
  - Limited claims can be made
    - Health
    - Nutrient content
    - Structure/function \(\rightarrow\) Disclaimer required
  - Not FDA “approved” for safety or efficacy prior to marketing
  - Good Manufacturing Practices (GMP), but still variable quality control
  - Advertising regulated by the Federal Trade Commission (FTC)
Quality Considerations

- Properly manufactured, contains the ingredients listed on the label, and does not contain harmful amounts of contaminants
- Independent organizations provide voluntary certification
  - U.S. Pharmacopeia (USP)
  - ConsumerLab.com
  - National Sanitation Foundation (NSF) International
  - Natural Products Association- TruLabel
  - Good Housekeeping Institute
- Seals of approval do NOT guarantee product safety/efficacy

Dietary Supplement Label

- General information
- Supplement facts panel
  - Proprietary blends
- Other ingredients
- Must include required criteria to avoid misbranding

General Safety Considerations

- Side effects
- Drug interactions
- Use caution in pregnancy, nursing, and children
- Manufacturer’s responsibility to ensure safety
  - Government efforts to improve public safety
- Report adverse reactions
  - 800-FDA-1088 or online Medwatch form
  - www.safetyreporting.hhs.gov

General Efficacy Considerations

- Efficacy vs. effectiveness
- Supplements do not replace a healthy diet
- Benefits for overall health and some conditions
  - Calcium and Vitamin D
  - Folic acid
  - Omega-3 fatty acids from fish oils
- Limited definitive information on bioactives in botanicals
- Ongoing study required → government funded grants available
Common Dietary Supplements

- Coenzyme Q10
- Omega-3/Fish Oil
- Cinnamon
- St. John’s Wort
- Echinacea
- Saw palmetto
- Glucosamine and chondroitin
- Vitamin C
- Vitamin D
- Vitamin B12
- Folate
- Calcium
- Iron

Coenzyme Q10

Efficacy
- May have cardiovascular benefits
- Inconclusive evidence
  - Statin muscle weakness
  - Reproductive disorders
  - Cancer

Safety
- No serious side effects
- Insomnia, increased liver enzymes, rash, nausea, upper abdominal pain, dizziness, sensitivity to light, irritability, headache, heartburn, fatigue
- May make warfarin less effective


Omega-3 Fatty Acids

Efficacy
- Fish oil improves blood lipids
- Appear to reduce risk of cardiovascular death
- Potential in other conditions

Safety
- Mostly gastrointestinal (GI) side effects
- Antiplatelet effects at high doses
- Dose limits
  - 3g/day EPA and DHA combined, up to 2g/day from dietary supplements


Cinnamon

Efficacy
- People use for:
  - GI problems
  - Loss of appetite
  - Diabetes
  - Research doesn’t support use

Safety
- Potential for allergic reaction
- Short-term use in small amounts
- Coumarin – liver disease
- Delay in medical care

St. John’s Wort

**Efficacy**
- Some evidence, not definitive
- Mild to moderate major depressive disorder

**Safety**
- Drug interactions (CYP 3A4)!
- Serotonin syndrome
- Possible psychosis
- Worsen anxiety
- Minor: sunlight sensitivity, upset stomach

Echinacea

**Efficacy**
- Use: treat colds
- Weak evidence
- Potential effect
- Clinical relevance?

**Safety**
- Few side effects
- Risk of rash (higher in children)

Saw Palmetto

**Efficacy**
- Use: symptoms of BPH
- Small studies: modest benefit
- Cochrane review: no more effective than placebo

**Safety**
- Well-tolerated
- Mild side effects
- Stomach discomfort

Glucosamine and Chondroitin

**Efficacy**
- Use: osteoarthritis
  - Knee or hip
  - Conflicting results
  - Sulfate > Hydrochloride

**Safety**
- Shellfish allergy
- No serious side effects
- May interact with warfarin
- Animal studies: kidney
Vitamin C

- Antioxidant used for immune health and wound healing
- Inconsistent evidence on cancer risk, protection against cardiovascular disease and macular degeneration
- Shorten common cold duration
- Deficiency leads to scurvy
- Low toxicity
- GI disturbances

| Table 1: Recommended Dietary Allowances (RDAs) for Vitamin C (mg) |
|-----------------|-----------------|-----------------|-----------------|
| Age             | Male            | Female          | Pregnancy       |
| 0-6 months      | 40 mg           | 40 mg           |                 |
| 7-12 months     | 50 mg           | 50 mg           |                 |
| 1-3 years       | 15 mg           | 15 mg           |                 |
| 4-8 years       | 25 mg           | 25 mg           |                 |
| 9-13 years      | 45 mg           | 45 mg           |                 |
| 14-18 years     | 75 mg           | 60 mg           | 80 mg           | 115 mg |
| 19-59 years     | 90 mg           | 75 mg           | 85 mg           | 120 mg |
| Smokers         | Individuals who smoke require 35 mg/day more vitamin C than non-smokers. |

* Adequate Intake (A)


Vitamin D

- Fat-soluble vitamin
- Exogenous and endogenous
- Bone growth and remodeling
- Calcium absorption
- Status: serum concentration 25(OH)D

| Table 1: Serum 25-Hydroxyvitamin D [25(OH)D] Concentrations and Health* |
|-----------------|---------------|
| nmoles/L | ng/mL |
| <30     | <12          |

* Associated with vitamin D deficiency, leading to rickets in infants and children and osteomalacia in adults


Vitamin D (continued)

- Supplements
  - D2 (ergocalciferol)
  - D3 (cholecalciferol)
- Deficiency: Rickets, osteomalacia
- Groups at risk inadequacy
- Toxicity symptoms
- Drug interactions

Vitamin B12

- Water soluble
- RBC formation, neurological function, DNA synthesis
- Signs/Symptoms deficiency
- Groups at risk for deficiency
- Low risk toxicity
- Drug interactions

| Table 1: Recommended Dietary Allowances (RDAs) for Vitamin B12 [μg] |
|-----------------|-----------------|-----------------|-----------------|
| Age             | Male            | Female          | Pregnancy       |
| 0-6 months      | 0.4 μg          | 0.4 μg          |                 |
| 7-12 months     | 0.5 μg          | 0.5 μg          |                 |
| 1-3 years       | 0.9 μg          | 0.9 μg          |                 |
| 4-5 years       | 1.2 μg          | 1.2 μg          |                 |
| 6-13 years      | 1.8 μg          | 1.8 μg          |                 |
| 14+ years       | 2.4 μg          | 2.4 μg          | 2.6 μg          | 2.8 μg |

* Adequate Intake

Folate

- Water soluble B vitamin
- Coenzyme or substrate
- Variety of products
- Risk for folate inadequacy
- Alcohol dependence
- Women of childbearing age (neural tube defects)
- Safety considerations
- Drug interactions

### Table 1: Recommended Dietary Allowances (RDAs) for Folate [2]

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female</th>
<th>Pregnant</th>
<th>Lactating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 6 months</td>
<td>65 mcg DFE</td>
<td>65 mcg DFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–12 months</td>
<td>80 mcg DFE</td>
<td>80 mcg DFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3 years</td>
<td>110 mcg DFE</td>
<td>110 mcg DFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–8 years</td>
<td>200 mcg DFE</td>
<td>200 mcg DFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9–13 years</td>
<td>300 mcg DFE</td>
<td>300 mcg DFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14–18 years</td>
<td>400 mcg DFE</td>
<td>400 mcg DFE</td>
<td>600 mcg DFE</td>
<td>500 mcg DFE</td>
</tr>
<tr>
<td>19+ years</td>
<td>600 mcg DFE</td>
<td>600 mcg DFE</td>
<td>800 mcg DFE</td>
<td>700 mcg DFE</td>
</tr>
</tbody>
</table>

* Adequate Intake (AI)

Calcium

- Mineral
- Involved in multiple physiological pathways
- Carbonate (40% elemental) vs. Citrate (21% elemental)
- Vitamin D required for absorption
- Groups at risk for inadequacy
- Risks with excessive

### Table 1: Recommended Dietary Allowances (RDAs) for Calcium [1]

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female</th>
<th>Pregnant</th>
<th>Lactating</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–6 months</td>
<td>200 mg</td>
<td>200 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–12 months</td>
<td>250 mg</td>
<td>250 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3 years</td>
<td>700 mg</td>
<td>700 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–8 years</td>
<td>1,000 mg</td>
<td>1,000 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9–13 years</td>
<td>1,300 mg</td>
<td>1,300 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14–18 years</td>
<td>1,300 mg</td>
<td>1,300 mg</td>
<td>1,300 mg</td>
<td>1,300 mg</td>
</tr>
<tr>
<td>19–50 years</td>
<td>1,000 mg</td>
<td>1,000 mg</td>
<td>1,000 mg</td>
<td>1,000 mg</td>
</tr>
<tr>
<td>51+ years</td>
<td>1,200 mg</td>
<td>1,200 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Adequate Intake (AI)

Iron

- Mineral
- Essential component of hemoglobin
- Iron deficiency anemia
  - Hgb < 13 g/dL men
  - Hgb < 12 g/dL women
- GI side effects

### Table 1: Recommended Dietary Allowances (RDAs) for Iron [3]

<table>
<thead>
<tr>
<th>Age</th>
<th>Male</th>
<th>Female</th>
<th>Pregnancy</th>
<th>Lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 6 months</td>
<td>0.27 mg</td>
<td>0.27 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7–12 months</td>
<td>11 mg</td>
<td>11 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–3 years</td>
<td>7 mg</td>
<td>7 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4–8 years</td>
<td>10 mg</td>
<td>10 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9–13 years</td>
<td>9 mg</td>
<td>9 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14–18 years</td>
<td>15 mg</td>
<td>15 mg</td>
<td>27 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>19–50 years</td>
<td>18 mg</td>
<td>18 mg</td>
<td>27 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>51+ years</td>
<td>8 mg</td>
<td>8 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Adequate Intake (AI)

Iron (continued)

- Supplement forms
  - Ferrous fumarate = 33% elemental iron
  - Ferrous sulfate = 20% elemental iron
  - Ferrous gluconate = 12% elemental iron
- Risk for iron inadequacy in certain populations
- Risk of high dose iron – children
- Drug interactions


Image source: https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/


Image source: https://ods.od.nih.gov/factsheets/Calcium-HealthProfessional/


Reputable Resources

- Office of Dietary Supplements (ODS)
- National Center for Complementary and Integrative Health (NCCIH)
- Operation Supplement Safety (OPSS) → App available
- Center for Drug Evaluation and Research (CDER)
- Dietary Supplement Databases
  - Dietary Supplement Label Database, Dietary Supplement Ingredient Database, and Computer Access to Research on Dietary Supplements (CARDS) Database
- FDA
- Medline Plus
- PubMed

Tips for Your Patients

- Use non-commercial sites for product information
  - Be cautious of information from sellers
- Look for seals of approval
  - Select well known manufacturers
- Avoid products that display these claims:
  - “works better than...” “totally safe” “no side effects”
  - “Natural” does not always mean “safe”
- Ask a healthcare professional if the product is beneficial/safe

Summary

- Dietary supplements are not regulated the same as prescription drug products
  - 1994 Dietary Supplement Health and Education Act (DSHEA)
- Various products on the market are not all equivalent
  - Gold-standard clinical trial data evaluating safety/efficacy is lacking
  - Some products have shown potential efficacy benefits
  - Always consider safety: Absence of evidence is not evidence of absence
- Reputable resources are available to guide therapy recommendations and patient care

Questions?