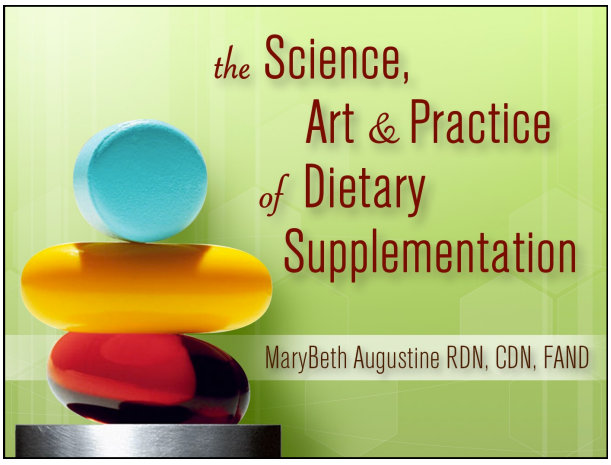
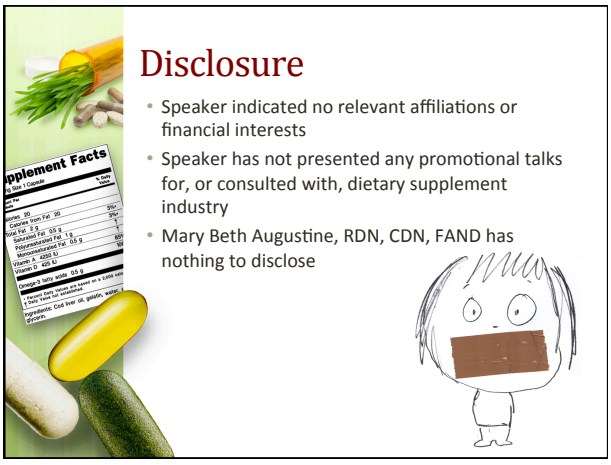
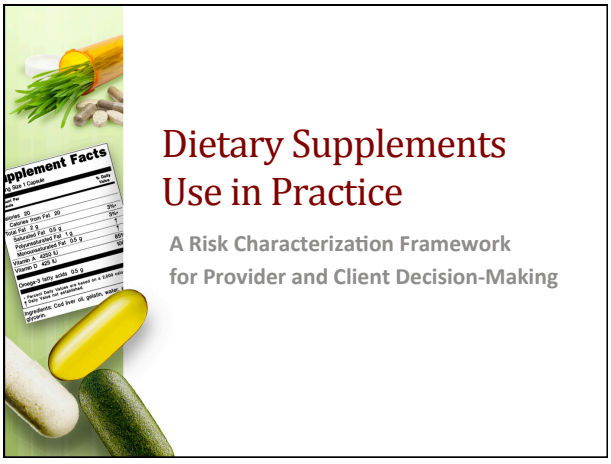
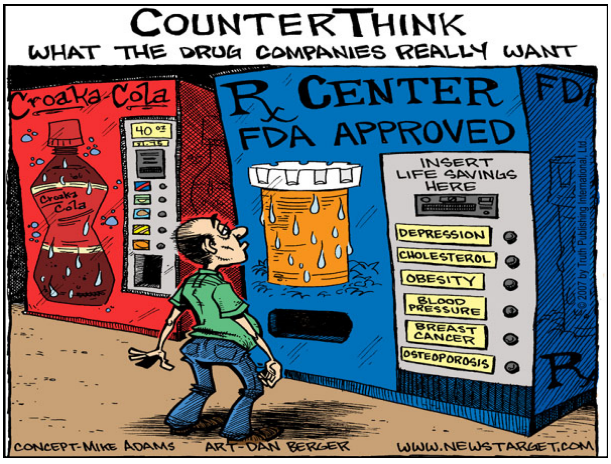

the Science,
Art & Practice
of Dietary
Supplementation
MaryBeth Augustine RDN, CDN, FAND


Disclosure
Speaker indicated no relevant affiliations or financial interests
Speaker has not presented any promotional talks for, or consulted with, dietary supplement industry
Mary Beth Augustine, RDN, CDN, FAND has nothing to disclose


Dietary Supplements
Use in Practice
A Risk Characterization Framework
for Provider and Client Decision-Making


COUNTERTHINK
WHAT THE DRUG COMPANIES REALLY WANT
Croaka-Cola
Rx CENTER
FDA APPROVED
INSERT LIFE SAVINGS HERE
DEPRESSION
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OBESITY
BLOOD PRESSURE
BREAST CANCER
OSTEOPOROSIS
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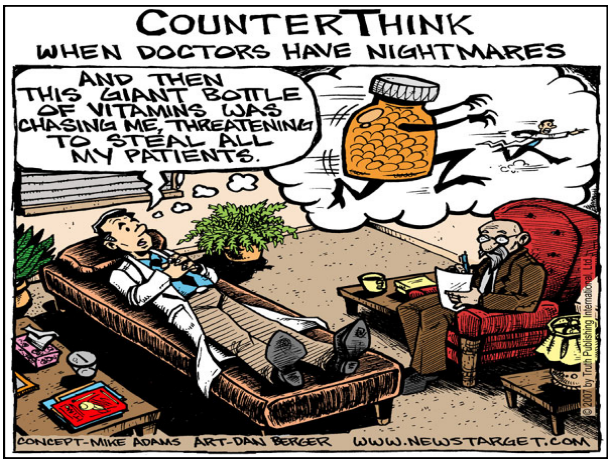
COUNTERTHINK
WHEN DOCTORS HAVE NIGHTMARES
AND THEN THIS GIANT BOTTLE OF VITAMINS WAS CHASING ME, THREATENING TO STEAL ALL MY PATIENTS.
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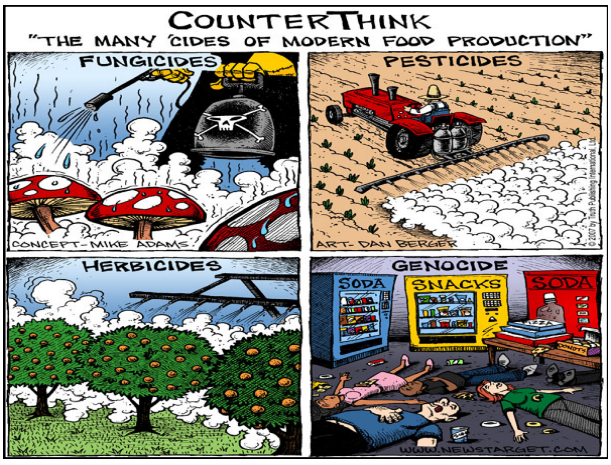
COUNTERTHINK
"THE MANY 'CIDES OF MODERN FOOD PRODUCTION"
FUNGICIDES
PESTICIDES
HERBICIDES
GENOCIDE
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SNACKS
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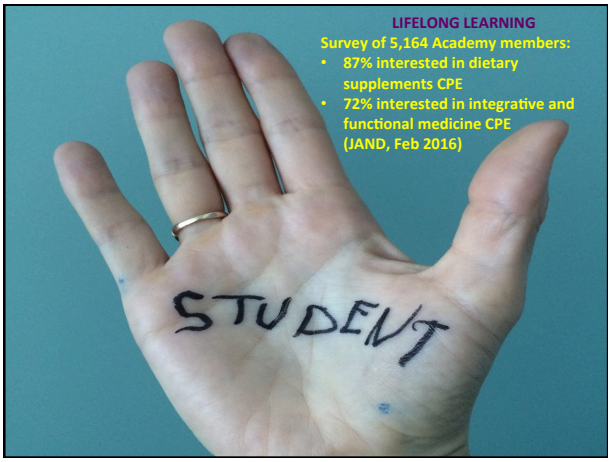
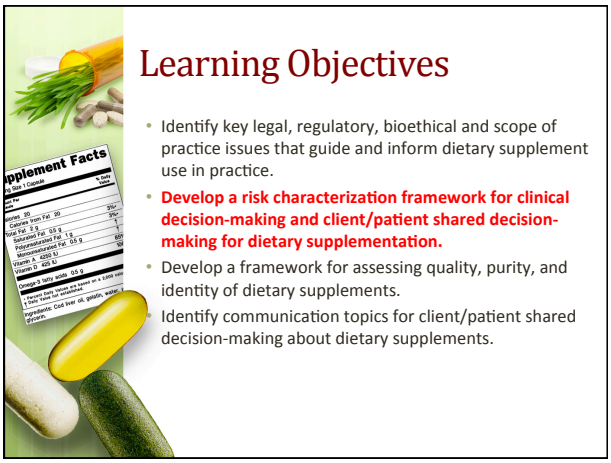
Manitoba Harvest, Hemp Oil, 1000 mg, 60 Softgel Capsules

Twinlab, Ultra GLA 300, 60 Softgels

Doctor's Best, Acetyl-L-Carnitine, 500 mg, 120 Veggie Caps

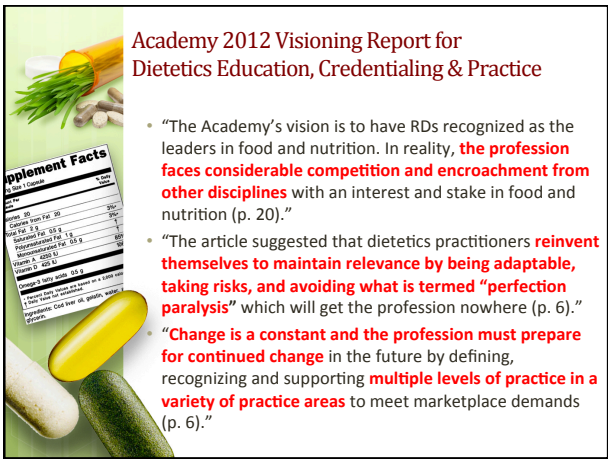
Nature's Way, Slippery Elm Bark, 400 mg, 100 Capsules





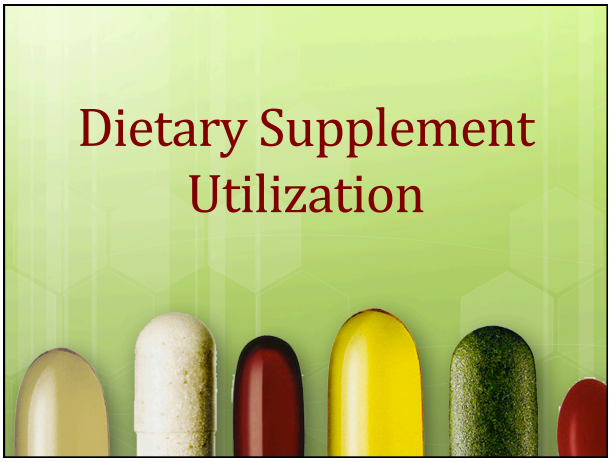
Learning Objectives

- Identify key legal, regulatory, bioethical and scope of practice issues that guide and inform dietary supplement use in practice.
- **Develop a risk characterization framework for clinical decision-making and client/patient shared decision-making for dietary supplementation.**
- Develop a framework for assessing quality, purity, and identity of dietary supplements.
- Identify communication topics for client/patient shared decision-making about dietary supplements.

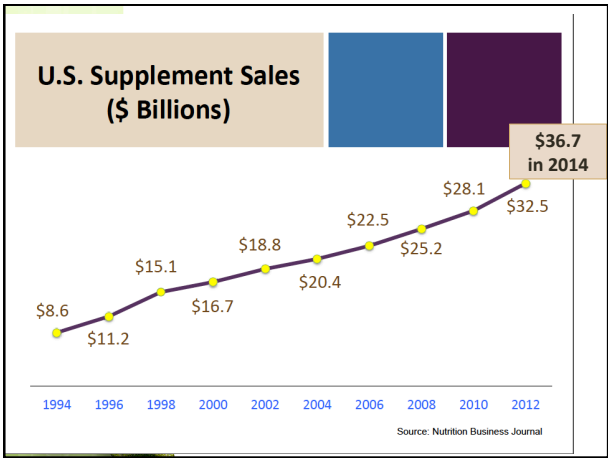


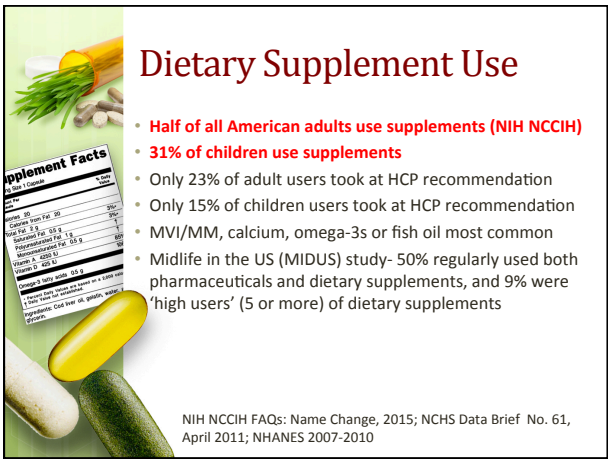
Academy 2012 Visioning Report for Dietetics Education, Credentialing & Practice

- "The Academy's vision is to have RDs recognized as the leaders in food and nutrition. In reality, **the profession faces considerable competition and encroachment from other disciplines** with an interest and stake in food and nutrition (p. 20)."
- "The article suggested that dietetics practitioners **reinvent themselves to maintain relevance by being adaptable, taking risks, and avoiding what is termed "perfection paralysis"** which will get the profession nowhere (p. 6)."
- "**Change is a constant and the profession must prepare for continued change** in the future by defining, recognizing and supporting **multiple levels of practice in a variety of practice areas** to meet marketplace demands (p. 6)."



Dietary Supplement Utilization

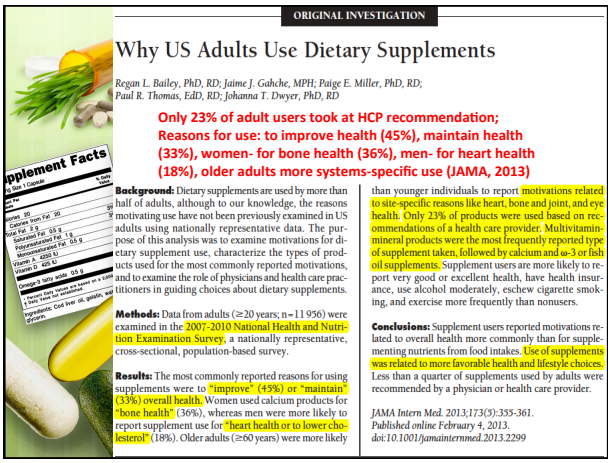




Dietary Supplement Use

- **Half of all American adults use supplements (NIH NCCIH)**
- **31% of children use supplements**
- Only 23% of adult users took at HCP recommendation
- Only 15% of children users took at HCP recommendation
- MVI/MM, calcium, omega-3s or fish oil most common
- Midlife in the US (MIDUS) study- 50% regularly used both pharmaceuticals and dietary supplements, and 9% were 'high users' (5 or more) of dietary supplements

NIH NCCIH FAQs: Name Change, 2015; NCHS Data Brief No. 61, April 2011; NHANES 2007-2010



ORIGINAL INVESTIGATION

Why US Adults Use Dietary Supplements

Regan L. Bailey, PhD, RD; Jaime J. Gahche, MPH; Paige E. Miller, PhD, RD; Paul R. Thomas, EdD, RD; Johanna T. Dwyer, PhD, RD

Only 23% of adult users took at HCP recommendation; Reasons for use: to improve health (45%), maintain health (33%), women- for bone health (36%), men- for heart health (18%), older adults more systems-specific use (JAMA, 2013)

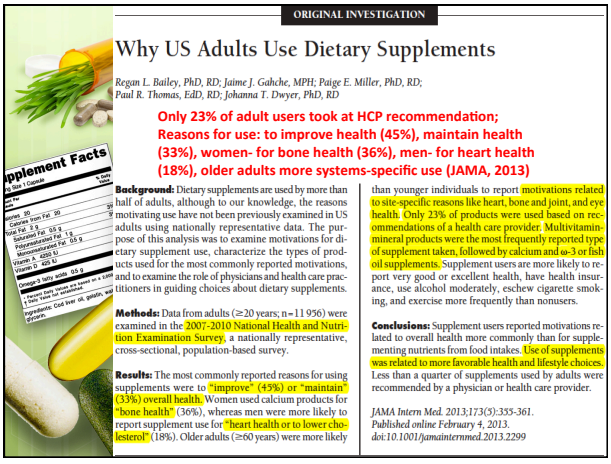
Background: Dietary supplements are used by more than half of adults, although to our knowledge, the reasons motivating use have not been previously examined in US adults using nationally representative data. The purpose of this analysis was to examine motivations for dietary supplement use, characterize the types of products used for the most commonly reported motivations, and to examine the role of physicians and health care practitioners in guiding choices about dietary supplements.

Methods: Data from adults (≥20 years; n=11 956) were examined in the 2007-2010 National Health and Nutrition Examination Survey, a nationally representative, cross-sectional, population-based survey.

Results: The most commonly reported reasons for using supplements were to "improve" (45%) or "maintain" (33%) overall health. Women used calcium products for "bone health" (36%), whereas men were more likely to report supplement use for "heart health or to lower cholesterol" (18%). Older adults (≥60 years) were more likely than younger individuals to report motivations related to site-specific reasons like heart, bone and joint, and eye health. Only 23% of products were used based on recommendations of a health care provider. Multivitamin-mineral products were the most frequently reported type of supplement taken, followed by calcium and ω-3 or fish oil supplements. Supplement users are more likely to report very good or excellent health, have health insurance, use alcohol moderately, eschew cigarette smoking, and exercise more frequently than nonusers.

Conclusions: Supplement users reported motivations related to overall health more commonly than for supplementing nutrients from food intakes. Use of supplements was related to more favorable health and lifestyle choices. Less than a quarter of supplements used by adults were recommended by a physician or health care provider.

JAMA Intern Med. 2013;173(5):355-361. Published online February 4, 2013. doi:10.1001/jamainternmed.2013.2299



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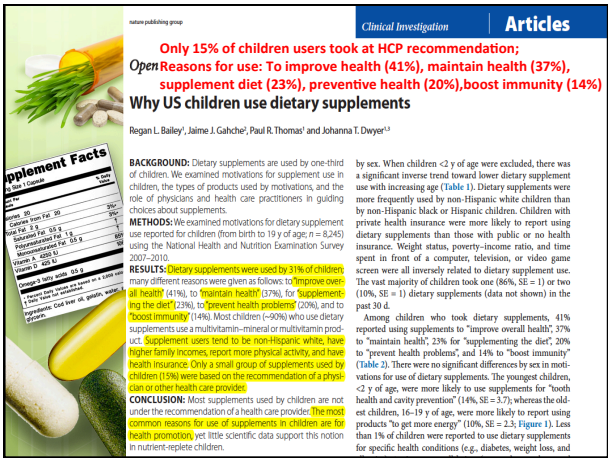

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Only 15% of children users took at HCP recommendation; Reasons for use: To improve health (41%), maintain health (37%), supplement diet (23%), preventive health (20%),boost immunity (14%)

Why US children use dietary supplements

Regan L. Bailey[1], Jaime J. Gahche[2], Paul R. Thomas[1] and Johanna T. Dwyer[1,3]

BACKGROUND: Dietary supplements are used by one-third of children. We examined motivations for supplement use in children, the types of products used by motivations, and the role of physicians and health care practitioners in guiding choices about supplements.

METHODS: We examined motivations for dietary supplement use reported for children (from birth to 19 y of age; *n* = 8,245) using the National Health and Nutrition Examination Survey 2007–2010.

RESULTS: Dietary supplements were used by 31% of children; many different reasons were given as follows: to "improve overall health" (41%), to "maintain health" (37%), for "supplementing the diet" (23%), to "prevent health problems" (20%), and to "boost immunity" (14%). Most children (>90%) who use dietary supplements use a multivitamin–mineral or multivitamin product. Supplement users tend to be non-Hispanic white, have higher family incomes, report more physical activity, and have health insurance. Only a small group of supplements used by children (15%) were based on the recommendation of a physician or other health care provider.

CONCLUSION: Most supplements used by children are not under the recommendation of a health care provider. The most common reasons for use of supplements in children are for health promotion, yet little scientific data support this notion in nutrient-replete children.

by sex. When children <2 y of age were excluded, there was a significant inverse trend toward lower dietary supplement use with increasing age (Table 1). Dietary supplements were more frequently used by non-Hispanic white children than by non-Hispanic black or Hispanic children. Children with private health insurance were more likely to report using dietary supplements than those with public or no health insurance. Weight status, poverty–income ratio, and time spent in front of a computer, television, or video game screen were all inversely related to dietary supplement use. The vast majority of children took one (86%, SE = 1) or two (10%, SE = 1) dietary supplements (data not shown) in the past 30 d.

Among children who took dietary supplements, 41% reported using supplements to "improve overall health", 37% to "maintain health", 23% for "supplementing the diet", 20% to "prevent health problems", and 14% to "boost immunity" (Table 2). There were no significant differences by sex in motivations for use of dietary supplements. The youngest children, <2 y of age, were more likely to use supplements for "tooth health and cavity prevention" (14%, SE = 3.7), whereas the oldest children, 16–19 y of age, were more likely to report using products "to get more energy" (10%, SE = 2.3; Figure 1). Less than 1% of children were reported to use dietary supplements for specific health conditions (e.g., diabetes, weight loss, and

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Dietary Supplement Use by Children and Adolescents in the United States to Enhance Sport Performance

Results of the National Health Interview Survey

Marion Willard Evans Jr., Harrison Ndetan, Michael Perko, Ronald Williams, Clark Walker

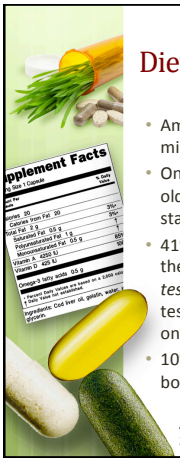
J Prim Prev. 2012;33(1):3-12.

Abstract and Introduction

N=9,417; national population estimate = 1.2 million kids are using DS to enhance sports performance; most commonly used DS are MV/MM (95%), fish oil/n-3s (44%), creatine (34%), fiber (26%)

Abstract

Dietary supplements may improve sport performance in adults. However, this has not been established in children. The aim of this study was to assess self-reported or parental-reported dietary supplement use to enhance sports performance among the child subset of the National Health Interview Survey (NHIS) dataset and determine national population estimates for that use. NHIS 2007 Child Alternative Medicine files containing records for children aged <18 years were used. Typical demographic variables were utilized as well as parental presence; parental education level; use of any herb, vitamin, and/or mineral use for sports performance by children; and age. Most (94.5%) who reported using supplements used multivitamin and/or mineral combinations followed by fish oil/omega-3 s, creatine, and fiber. Males were more likely users (OR = 2.1; 95% CI [1.3, 3.3]), and Whites reported greater usage. Mean user age was 10.8 (*SD* = 0.2) with 57.7% >10 years, indicating some increase in use with higher age categories ($p < .001$). Most were US born and reported living with both parents. Parents and children report child use of a wide variety of herbal and vitamin/mineral supplements to improve sports performance. Usage could be predicted by age, gender, and level of education but less likely by parent-based demographics.



Dietary Supplements: Sales to Minors

- American Academy of Pediatrics recommends against minors using body-shaping DS
- One study of testers identifying themselves as 15-year-old boys and girls called 244 natural food stores in 49 states
- 41% of store employees told callers identifying themselves as 15-year-olds that *they could buy testosterone boosters on their own* despite many testosterone boosters' labels indicating 'for adult use only'
- 10% of store employees *recommended* a testosterone booster to callers identifying themselves as 15-year-olds

Accessed October 2015 from http://www.eurekalert.org/pub_releases/2015-04/nsij-dwh042315.php

JGIM

BRIEF REPORTS **Nearly 80% of hospitalized patients report use of DS**

Use of and Communication about Dietary Supplements Among Hospitalized Patients

Laura A. Young, MD, PhD[1,3], Keturah R. Faurot, PA, MPH[2], and Susan A. Gaylord, PhD[2]

[1]Department of Internal Medicine, University of Pennsylvania, Philadelphia, USA; [2]Department of Physical Medicine and Rehabilitation, University of North Carolina School of Medicine, Philadelphia, USA; [3]Clinical Associate Faculty in Endocrinology, Diabetes and Metabolism, One Maloney Building, Endocrinology Practice, Philadelphia, PA, USA.

BACKGROUND: Use of dietary supplements (DS) is common in the United States; however little is known about the use of DS specifically in hospitalized patients.

OBJECTIVE: The goal of this study is to begin to characterize trends in DS use by hospitalized patients and to assess the degree of patient-physician communication about use of DS that occurs during hospitalization.

DESIGN: This is a cross-sectional, observational pilot study.

PARTICIPANTS: Participants were admitted to the general internal medicine or geriatrics service by house staff residents; those ≥ 18 years of age who were medically stable, cognitively intact and fluent in English and/or Spanish were invited to participate in the study.

RESULTS: Nearly 80% of hospitalized patients reported use of DS, with 52% reporting use of non-vitamin/non-mineral DS. During the admission process, physicians documented inquiring about DS use only 20% of the time. While the majority of patients had no concern about temporarily discontinuing their DS during hospitalization, 13% of patients reported that they believed there was nothing wrong with continued use of DS while hospitalized regardless of the recommendations provided by their inpatient physicians.

CONCLUSIONS: Use of DS in hospitalized patients is common, and communication between patients and physicians regarding their use is limited

between patients and physicians addressing this topic [3]. The literature documenting trends in the utilization of DS and disclosure of use to physicians has been predominantly in the outpatient setting [4–6]. Although the use of DS is more common among patients who have been hospitalized within the past 12 months, specifics about use of DS in these patients are lacking [7]. The purpose of this pilot study was to characterize DS use by hospitalized patients, evaluate patient–physician communication about use of DS during the hospital admission process, and document patients' attitudes and expectations about DS use while hospitalized.

METHODS

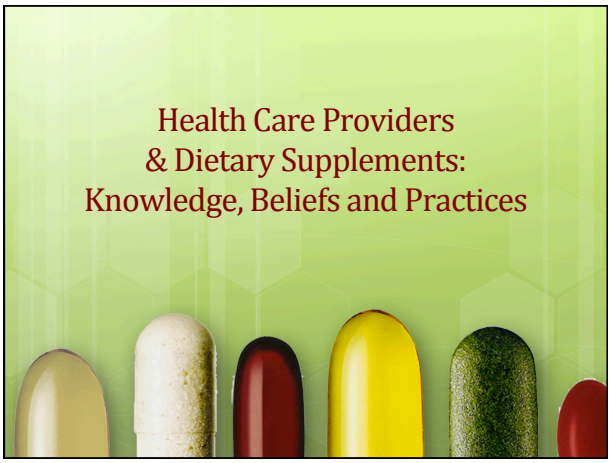
Subjects. Eligible patients admitted by internal medicine house staff residents to the medicine and geriatric services at the University of North Carolina (UNC) Medical Center were invited to participate in the survey. Eligibility criteria included: age ≥ 18 years, medically stable (i.e., not in an ICU or being evaluated for ICU admission), cognitively intact, and conversant in English or Spanish. Patients in isolation were excluded. Approval for the study was granted by the UNC IRB.

Data Collection. Within 72 hours of admission, nurses identified eligible patients and obtained permission for

Botanical/Herbal Supplement Users

- More likely to be uninsured
- Use more prescription and OTC medications
- Use is disease-specific and etiology-driven
- Less likely to disclose use to HCPs

Source: JAMA 2013 173(5), 355-361.



RESEARCH

N= 162; knowledge, confidence, and communication gaps identified- higher for herbal DS than nutrient DS and functional foods, high interest in CPE (2000)

The knowledge, attitudes, and practices of dietitians licensed in Oregon regarding functional foods, nutrient supplements, and herbs as complementary medicine

YI-KYOUNG LEE, MS, RD[1]; CONSTANCE GEORGIOU, PhD, RD; CAROLYN RAAB, PhD, RD

ABSTRACT

Objective To examine the perceived knowledge and attitudes of dietitians licensed in Oregon (LDs) regarding the effectiveness and safety of functional foods, nutrient supplements, and herbs as complementary medicine as well as their personal use, recommendations for the use of others, and training needs.
Design A mailed survey was used to gather data. The questionnaire was developed and face-validated after a focus group discussion.

Use of complementary medicine in the United States has increased dramatically in recent years. According to a nationwide telephone survey conducted in 1991, 1 in 3 Americans used at least 1 unconventional medical treatment during the previous year (1). More recent studies have reported that the percentage of the general public (2-4) and family practice medical patients (5) who use some forms of complementary medicine has grown to as much as 50%.

Complementary medicine, also called alternative medicine, was defined less than a decade ago as any medical practice or intervention that is not widely taught at US medical schools (1) or is not generally reimbursable by health insurance providers

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 9, Number 5, 2003, pp. 735–746

N= 158; 73% reported 'little or no knowledge' of herbs, 37% reported self-use of herbs, and 22% reported practice-use of herbs (2003)

Massachusetts Registered Dietitians' Knowledge, Attitudes, Opinions, Personal Use, and Recommendations to Clients About Herbal Supplements

LINDA S. CASHMAN, M.S., R.D., C.N.S.D.,[1] JEANMARIE T. BURNS, M.S., R.D.,[2] IRENE M. OTIENO, M.S., R.D.,[3] and TERESA FUNG, Sc.D., R.D.[4]

ABSTRACT

Objective: To assess the knowledge, personal use and recommendations of herbal supplements among registered dietitians (RDs) in Massachusetts.
Design: A descriptive, cross-sectional study conducted by a self-administered survey.
Subjects: One hundred and fifty-eight RDs from active members of the Massachusetts Dietetic Association (MDA).

RESEARCH

N= 253; knowledge, confidence, and communication gaps identified- those reporting formal training scored higher in all three (2006)

Research and Professional Briefs

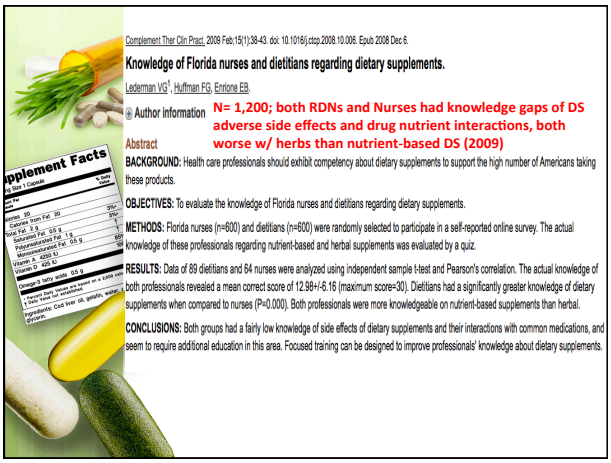
Perceived Knowledge, Attitudes, and Practices of California Registered Dietitians Regarding Dietary Supplements

CHAD HETHERWICK, MS, RD; MICHELLE NEYMAN MORRIS, PhD, RD; KATHRYN SILLIMAN, PhD, RD

ABSTRACT
A convenience sample of California registered dietitians (RDs) (n=253) completed a survey investigating the perceived knowledge, attitudes, and practices of RDs who had or had not received formal training in use of dietary supplements. We also examined whether differences existed between RDs registered before or after 1997, when the American Dietetic Association began requiring that dietetics curricula include basic knowledge of dietary supplements. Statistical analysis included analysis of variance and χ^2 analysis. Among this sample of RDs from California, those registered before 1997 (n=194) were more likely ($P<0.05$) to agree that they are knowledgeable regarding supplement use, safety, interactions, and contraindications than those registered after 1997 (n=46), and were more likely ($P<0.05$) to assess client use. Among this sample of RDs from California, those reporting that they had received formal training in dietary supplements (n=145) were more likely ($P<0.05$)

alternative medicine therapies (1). The use of dietary supplements is among the most popular complementary and alternative medicine practices (1). The 2000 National Health Interview Survey indicated that 34% of adults used vitamin and/or mineral supplements daily, whereas 6% used nonvitamin/nonmineral supplements (3). Since the enactment of the Dietary Supplement Health Education Act (4) in 1994, sales of dietary supplements have doubled and in 2002 reached $18 billion (5,6).

Most dietary supplement users may not realize the potential for adverse effects (7,8) and health care providers may not be routinely asking patients about use of supplements. In 1997, the American Dietetic Association (ADA) acknowledged the need for educating registered dietitians (RDs) about complementary and alternative medicine in a *Journal of the American Dietetic Association* President's Page (9) and required that dietetics curricula include basic knowledge about alternative nutrition and dietary supplements (10). In 2001, ADA developed a position paper on the role of RDs regarding dietary supple-



Complement Ther Clin Pract. 2009 Feb;15(1):38-43. doi: 10.1016/j.ctcp.2008.10.006. Epub 2008 Dec 6.

Knowledge of Florida nurses and dietitians regarding dietary supplements.

Lederman VG[1], Huffman FG, Entione EB.

Author information

N= 1,200; both RDNs and Nurses had knowledge gaps of DS adverse side effects and drug nutrient interactions, both worse w/ herbs than nutrient-based DS (2009)

Abstract

BACKGROUND: Health care professionals should exhibit competency about dietary supplements to support the high number of Americans taking these products.

OBJECTIVES: To evaluate the knowledge of Florida nurses and dietitians regarding dietary supplements.

METHODS: Florida nurses (n=800) and dietitians (n=600) were randomly selected to participate in a self-reported online survey. The actual knowledge of these professionals regarding nutrient-based and herbal supplements was evaluated by a quiz.

RESULTS: Data of 89 dietitians and 64 nurses were analyzed using independent sample t-test and Pearson's correlation. The actual knowledge of both professionals revealed a mean correct score of 12.98+/-6.16 (maximum score=30). Dietitians had a significantly greater knowledge of dietary supplements when compared to nurses (P=0.000). Both professionals were more knowledgeable on nutrient-based supplements than herbal.

CONCLUSIONS: Both groups had a fairly low knowledge of side effects of dietary supplements and their interactions with common medications, and seem to require additional education in this area. Focused training can be designed to improve professionals' knowledge about dietary supplements.

Dickinson et al. Nutrition Journal 2012, 11:14
http://www.nutritionj.com/content/11/1/14

NUTRITION JOURNAL

RESEARCH Open Access

N= 300 private practice RDNs; 74% reported self-use of DS, and 97% reported practice-use of DS (2012)

Dietitians use and recommend dietary supplements: report of a survey

Annette Dickinson[1*], Leslie Bonci[2], Nicolas Boyon[3] and Julio C Franco[3]

Abstract

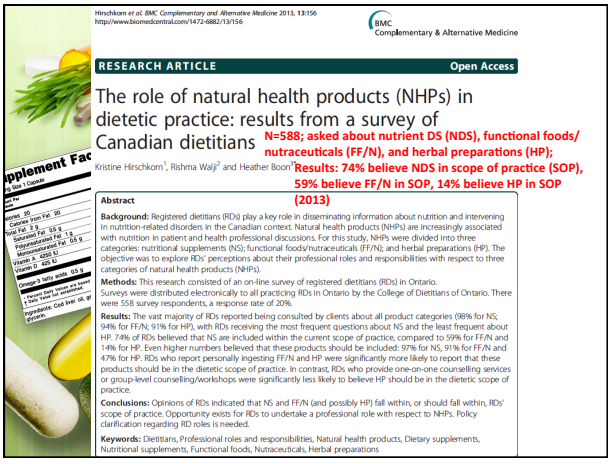
Background: Dietary supplement use is common in the United States, with more than half of the population using such products. Nutrition authorities consistently advocate a "food first" approach to achieving nutritional adequacy but some, including the Academy of Nutrition and Dietetics (formerly the American Dietetic Association), also recognize that dietary supplements have a role to play in improving nutrient intake to support health and wellness. Surveys show that many health professionals use dietary supplements themselves and also recommend dietary supplements to their patients or clients.

Methods: As one component of a series of surveys of healthcare professionals (the "Life...supplemented" HCP Impact Studies), 300 registered dietitians were surveyed in 2009 regarding their personal use of dietary supplements and whether they recommend dietary supplements to their clients. Respondents were registered dietitians whose business involved seeing clients in a private practice or at a clinic.

Results: Seventy-four percent of the dietitians surveyed said they were regular users of dietary supplements, while 22% said they used dietary supplements occasionally or seasonally. The primary reasons for using dietary supplements were for bone health (58%), overall health and wellness (53%), and to fill nutrient gaps (42%). When asked if they "ever recommend dietary supplements to clients," 97% of the respondents said they did. The primary reasons were for bone health (70%), to fill nutrient gaps (67%), and overall health and wellness (49%). Eighty-seven percent of the dietitians agreed with the statement, "There are gaps in clients' diets that could effectively be addressed with dietary supplements." The dietitians surveyed said they followed healthy habits including eating a balanced diet (96%), managing stress (92%), visiting their own healthcare professional regularly (86%), exercising regularly (83%), maintaining a healthy weight (80%), and getting a good night's sleep (72%). Nearly all respondents (95%) expressed an interest in continuing education about dietary supplements on a variety of topics.

Conclusions: Many dietitians, like other health professionals, use dietary supplements regularly as part of their own approach to a healthy diet and lifestyle. They also recommend dietary supplements to their clients or patients, to promote health.

Keywords: Dietary supplements, Supplement surveys, Dietitians' health habits



Hirschkorn et al. BMC Complementary and Alternative Medicine 2013, 13:156
http://www.biomedcentral.com/1472-6882/13/156

BMC Complementary & Alternative Medicine

RESEARCH ARTICLE Open Access

The role of natural health products (NHPs) in dietetic practice: results from a survey of Canadian dietitians

N=588; asked about nutrient DS (NDS), functional foods/ nutraceuticals (FF/N), and herbal preparations (HP); Results: 74% believe NDS in scope of practice (SOP), 59% believe FF/N in SOP, 14% believe HP in SOP (2013)

Kristine Hirschkorn[1], Rishma Walji[2] and Heather Boon[3]

Abstract

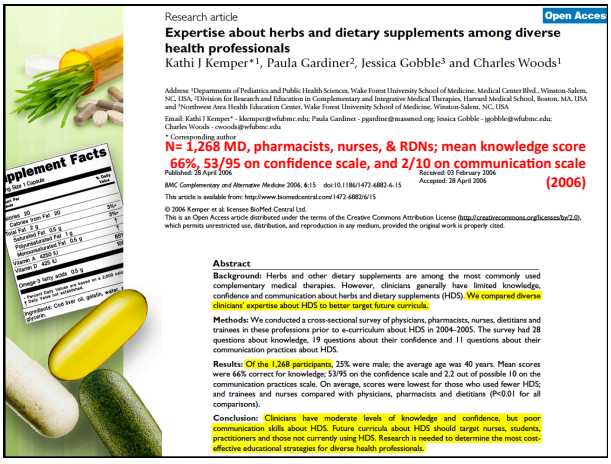
Background: Registered dietitians (RDs) play a key role in disseminating information about nutrition and intervening in nutrition-related disorders in the Canadian context. Natural health products (NHPs) are increasingly associated with nutrition in patient and health professional discussions. For this study, NHPs were divided into three categories: nutritional supplements (NS); functional foods/nutraceuticals (FF/N); and herbal preparations (HP). The objective was to explore RDs' perceptions about their professional roles and responsibilities with respect to three categories of natural health products (NHPs).

Methods: This research consisted of an on-line survey of registered dietitians (RDs) in Ontario. Surveys were distributed electronically to all practicing RDs in Ontario by the College of Dietitians of Ontario. There were 558 survey respondents, a response rate of 20%.

Results: The vast majority of RDs reported being consulted by clients about all product categories (98% for NS; 94% for FF/N; 91% for HP), with RDs receiving the most frequent questions about NS and the least frequent about HP. 74% of RDs believed that NS are included within the current scope of practice, compared to 59% for FF/N and 14% for HP. Even higher numbers believed that these products should be included: 97% for NS, 91% for FF/N and 47% for HP. RDs who report personally ingesting FF/N and HP were significantly more likely to report that these products should be in the dietetic scope of practice. In contrast, RDs who provide one-on-one counselling services or group-level counselling/workshops were significantly less likely to believe HP should be in the dietetic scope of practice.

Conclusions: Opinions of RDs indicated that NS and FF/N (and possibly HP) fall within, or should fall within, RDs' scope of practice. Opportunity exists for RDs to undertake a professional role with respect to NHPs. Policy clarification regarding RD roles is needed.

Keywords: Dietitians, Professional roles and responsibilities, Natural health products, Dietary supplements, Nutritional supplements, Functional foods, Nutraceuticals, Herbal preparations



Research article Open Access

Expertise about herbs and dietary supplements among diverse health professionals

Kathi J Kemper*[1], Paula Gardiner[2], Jessica Gobble[3] and Charles Woods[1]

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Email: Kathi J Kemper* - kkemper@wfubmc.edu; Paula Gardiner - pgardine@massmed.org; Jessica Gobble - jgobble@wfubmc.edu; Charles Woods - cwoods@wfubmc.edu

* Corresponding author

N= 1,268 MD, pharmacists, nurses, & RDNs; mean knowledge score 66%, 53/95 on confidence scale, and 2/10 on communication scale (2006)

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BMC Complementary and Alternative Medicine 2006, 6:15 doi:10.1186/1472-6882-6-15

This article is available from: http://www.biomedcentral.com/1472-6882/6/15

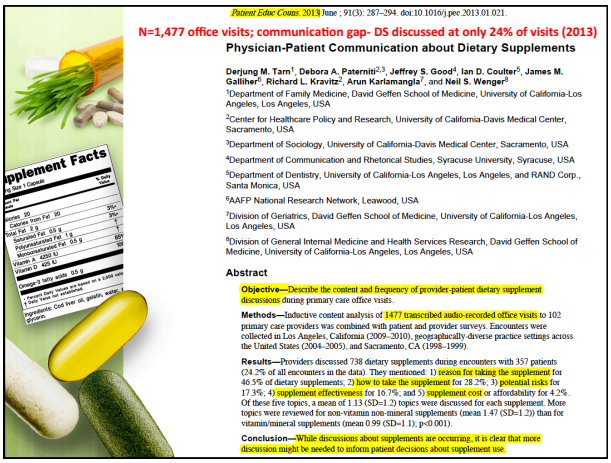
Abstract

Background: Herbs and other dietary supplements are among the most commonly used complementary medical therapies. However, clinicians generally have limited knowledge, confidence and communication about herbs and dietary supplements (HDS). We compared diverse clinicians' expertise about HDS to better target future curricula.

Methods: We conducted a cross-sectional survey of physicians, pharmacists, nurses, dietitians and trainees in these professions prior to e-curriculum about HDS in 2004–2005. The survey had 28 questions about knowledge, 19 questions about their confidence and 11 questions about their communication practices about HDS.

Results: Of the 1,268 participants, 25% were male; the average age was 40 years. Mean scores were 66% correct for knowledge, 53/95 on the confidence scale and 2.2 out of possible 10 on the communication practices scale. On average, scores were lowest for those who used fewer HDS; and trainees and nurses compared with physicians, pharmacists and dietitians (P<0.01 for all comparisons).

Conclusion: Clinicians have moderate levels of knowledge and confidence, but poor communication skills about HDS. Future curricula about HDS should target nurses, students, practitioners and those not currently using HDS. Research is needed to determine the most cost-effective educational strategies for diverse health professionals.



Patient Educ Couns. 2013 June ; 91(3): 287–294. doi:10.1016/j.pec.2013.01.021.

N=1,477 office visits; communication gap- DS discussed at only 24% of visits (2013)

Physician-Patient Communication about Dietary Supplements

Derjung M. Tarn[1], Debora A. Paterniti[2,3], Jeffrey S. Good[4], Ian D. Coulter[5], James M. Galliher[6], Richard L. Kravitz[2], Arun Karlamangla[7], and Neil S. Wenger[8]

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[5]Department of Dentistry, University of California-Los Angeles, Los Angeles, and RAND Corp., Santa Monica, USA

[6]AAFP National Research Network, Leawood, USA

[7]Division of Geriatrics, David Geffen School of Medicine, University of California-Los Angeles, Los Angeles, USA

[8]Division of General Internal Medicine and Health Services Research, David Geffen School of Medicine, University of California-Los Angeles, Los Angeles, USA

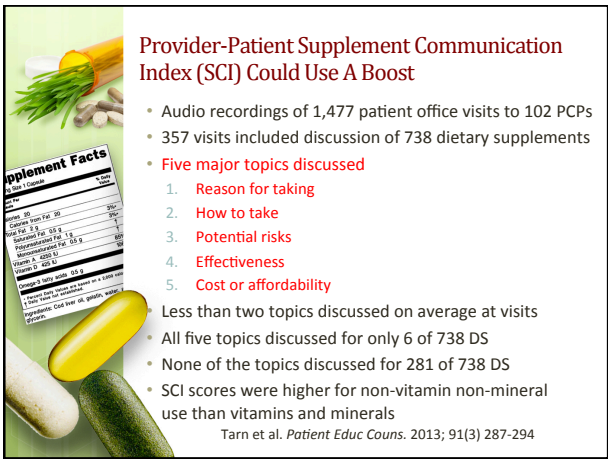
Abstract

Objective—Describe the content and frequency of provider-patient dietary supplement discussions during primary care office visits.

Methods—Inductive content analysis of 1477 transcribed audio-recorded office visits to 102 primary care providers was combined with patient and provider surveys. Encounters were collected in Los Angeles, California (2009–2010), geographically-diverse practice settings across the United States (2004–2005), and Sacramento, CA (1998–1999).

Results—Providers discussed 738 dietary supplements during encounters with 357 patients (24.2% of all encounters in the data). They mentioned: 1) reason for taking the supplement for 46.5% of dietary supplements; 2) how to take the supplement for 28.2%; 3) potential risks for 17.3%; 4) supplement effectiveness for 16.7%; and 5) supplement cost or affordability for 4.2%. Of these five topics, a mean of 1.13 (SD=1.2) topics were discussed for each supplement. More topics were reviewed for non-vitamin non-mineral supplements (mean 1.47 (SD=1.2)) than for vitamin/mineral supplements (mean 0.99 (SD=1.1); p<0.001).

Conclusion—While discussions about supplements are occurring, it is clear that more discussion might be needed to inform patient decisions about supplement use.



Provider-Patient Supplement Communication Index (SCI) Could Use A Boost

- Audio recordings of 1,477 patient office visits to 102 PCPs
- 357 visits included discussion of 738 dietary supplements
- Five major topics discussed
  1. Reason for taking
  2. How to take
  3. Potential risks
  4. Effectiveness
  5. Cost or affordability
- Less than two topics discussed on average at visits
- All five topics discussed for only 6 of 738 DS
- None of the topics discussed for 281 of 738 DS
- SCI scores were higher for non-vitamin non-mineral use than vitamins and minerals

Tarn et al. *Patient Educ Couns.* 2013; 91(3) 287-294

REVIEW

Knowledge gaps strain doctor-patient relationship; 6-step approach to advising patients: 1) discuss regulatory issues, 2) discuss efficacy, 3) discuss safety, 4) discuss drug-nutrient interactions, 5) monitor for adverse events, and 6) monitor for therapeutics effects

THE AMERICAN JOURNAL of MEDICINE®

Advising Patients Who Use Dietary Supplements

Bimal H. Ashar, MD, MBA, Anastasia Rowland-Seymour, MD

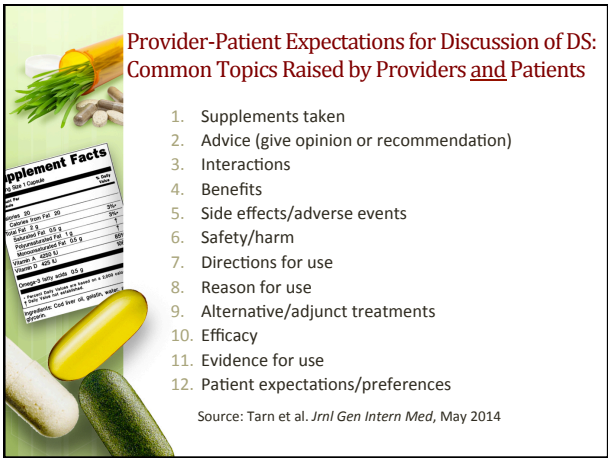
Division of General Internal Medicine, The Johns Hopkins University School of Medicine, Baltimore, Md.

ABSTRACT

Public use of dietary supplements is quite prevalent, with an estimated 1 of 5 patients using such substances in an effort to maintain or promote their health. Despite their popularity, patients and physicians are often unaware of the limited regulation of these products as well as their potential risks and benefits. Lack of physician knowledge in these areas has the potential to strain the doctor-patient relationship. In this review, we present a 6-step approach to advising patients who are considering use of dietary supplements. Our framework includes a discussion of regulatory issues, efficacy and safety, potential supplement-drug interactions, and monitoring for adverse events and therapeutic effects.

 • *The American Journal of Medicine (2008) 121, 91-97*

KEYWORDS: Complementary and alternative medicine; Dietary supplements; Herbal medicine



Provider-Patient Expectations for Discussion of DS: Common Topics Raised by Providers and Patients

1. Supplements taken
2. Advice (give opinion or recommendation)
3. Interactions
4. Benefits
5. Side effects/adverse events
6. Safety/harm
7. Directions for use
8. Reason for use
9. Alternative/adjunct treatments
10. Efficacy
11. Evidence for use
12. Patient expectations/preferences

Source: Tarn et al. *Jrnl Gen Intern Med*, May 2014

Provider-Patient Expectations for Discussion of DS

Topics Raised Predominantly by Providers

- Source of information
- Provider knowledge/experience with DS
- Cost/affordability
- Regulatory issues

Topics Raised Only by Patients & Complementary Providers

- Composition, purity and quality
- Natural versus synthetic
- Plant or animal based
- Mega dosing

Source: Tarn et al. *Jrnl Gen Intern Med*, May 2014

American Board of Physicians Specialties & American Board of Integrative Medicine

Offers Board Certification to physicians in integrative medicine
Inaugural exam held November 2014
Next exam May 2015

ABPS & ABOIM Exam Description
Integrative Medicine Exam Domains

1. **Nutrition:** macro/micronutrients, therapeutic diets, elimination diets, social/cultural influence on diet, environmental factors, functional foods (15%)
2. **Dietary Supplements/Botanicals:** adverse effects; drug interactions, safety, efficacy, evidence-base (15%)
3. **Mind-Body Medicine/Spirituality:** mental/emotional influence on health (stress, optimism, resilience, positive thinking), physical influences on mental health (sleep, exercise, diet), self-regulation therapies (biofeedback, hypnotherapy, meditation), spirituality and health (coping, attitudes, transpersonal healing), religion and health (beliefs, practices) (14%)
4. **CAM:** manipulative and body-based, energy medicine, movement therapies, expressive arts (10%)
5. **Whole Medical Systems:** TCM, Ayurveda, traditional medical systems, homeopathy, naturopathy (8%)
6. **Lifestyle/Prevention & Health Promotion:** social factors and health, barriers to change and MI, physical activity, environmental factors (exposures), risk reduction, self care, sleep, healthy/unhealthy behaviors (13%)
7. **Integrative Approaches** (including conventional medicine): women's/men's health, pediatrics, geriatrics, cardiovascular, GI, cancer, mental health, respiratory, dermatology, neurology, pain management, rheumatology, endocrine, infectious diseases, allergies, death and dying, palliative care (15%)
8. **Foundations of Integrative Medicine:** philosophy, history, ethics (5%)
9. **Professional Practice of Integrative Medicine:** prioritization, risk-benefit, doctor patient communications, evidence-based principles, medical/legal, cost effectiveness, critical assessment of unproven diagnostic and treatment methods (5%)

Academy of Nutrition and Dietetics Publications Addressing Dietary Supplements Scope of Practice

"IFMNT incorporates varied modalities such as therapeutic food elimination diets (28); dietary supplements, including vitamins, minerals, and botanicals;..."

from the association

Source: JADA, June 2011

American Dietetic Association: Standards of Practice and Standards of Professional Performance for Registered Dietitians (Competent, Proficient, and Expert) in Integrative and Functional Medicine

Deborah Ford, MS, RD; Sudha Raj, PhD, RD, CDN; Rita Kashi Batheja, MS, RD, CDN; Ruth DeBusk, PhD, RD, LDN; Dave Grotto, RD, LDN; Diana Noland, MPH, RD; Elizabeth Redmond, PhD, MMSc, RD, LD; Kathie Madonna Swift, MS, RD, LDN

Editor's note: Figures 1, 2 and 3 that accompany this article are available online at www.adajournal.org.

The Dietitians in Integrative and Functional Medicine (DIFM) Dietetic Practice Group (DPG) of the American Dietetic Association (ADA), under the guidance of the

Approved February 2011 by the Quality Management Committee of the American Dietetic Association (ADA) House of Delegates and the Executive Committee of the Dietitians in Integrative and Functional Medicine Dietetic Practice Group of the ADA. **Scheduled review date: June 2016.** Questions regarding the Standards of Practice and Standards of Professional Performance for RDs in Integrative and Functional Medicine may be addressed to ADA quality management staff: Sharon McCauley, MS, MBA, RD, LDN, FADA, director, Quality Management at quality@eatright.org.

***D. Ford** is owner, Good Earth Health Nutrition & Fitness, Van Wert, OH. **S. Raj** is a senior part-time instructor, Department of Nutrition Science and Dietetics, College of Human Ecology, Syra-*

ADA Quality Management Committee and its Scope of Dietetics Practice Framework Sub-Committee, has developed Standards of Practice (SOP) and Standards of Professional Performance (SOPP) for Registered Dieti-

dures; and individual competence, accountability, and responsibility for his or her own actions.

ADA's Revised 2008 SOP in Nutrition Care and SOPP reflect the mini-

eat right.

FROM THE ACADEMY

Scope of Practice

RD Roles: Integrative and functional medicine– *"RDs are skilled in functional and integrative medicine, nutritional genomics, whole foods, nutrition supplements and dietary supplements, and utilizing the NCP in a broad range of holistic and therapeutic modalities (p. S24)."*

Academy of Nutrition and Dietetics: Scope of Practice for the Registered Dietitian

The Academy Quality Management Committee and Scope of Practice Subcommittee of the Quality Management Committee

THE ACADEMY OF NUTRITION and Dietetics (Academy) is the world's largest organization of food and nutrition practitioners and the professional association for credentialed dietetics practitioners—registered dietitians (RDs) and dietetic technicians, registered (DTRs). The Academy's mission is to empower members to be the nation's food and nutrition leaders. The Scope of Practice for the Registered Dietitian reflects the position of the Academy on the essential role of the RD in the direction and delivery of food and nutrition services.

The Scope of Practice for the Registered Dietitian is used in conjunction with the Academy's Scope of Practice in Nutrition and Dietetics,[1] the 2012 Stan-

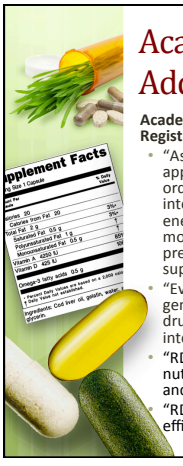
RDs are committed to optimizing the nation's health and advancing the profession of nutrition and dietetics through safe, person-centered, culturally competent, quality food and nutrition services. Food and nutrition services provided by RDs assist individuals and populations in developing and maintaining eating and lifestyle behaviors that enhance health and quality of life. RD services span a continuum that includes nutrition care, foodservice systems and food systems management, education, research, technology, business, communication, health promotion, disease prevention, and nutrition policy.

PURPOSE

Approved November 2012 by the Quality Management Committee of the Academy of Nutrition and Dietetics (Academy) and the Academy House of Delegates. Scheduled review date: November 2017.

Questions regarding the Scope of Practice for the Registered Dietitian may be addressed to the Academy Quality Management Staff: Karen Hui, RD, LDN, manager, Practice Standards; and Sharon M. McCauley, MS, MBA, RD, LDN, FADA, director, Quality Management at quality@eatright.org.

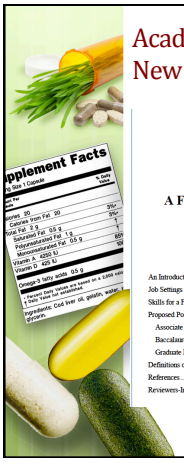
lators, insurers, business owners and managers, and the general public about the qualifications of the RD, competence, and professional services provided by RDs.



Academy Publications Addressing DS Use in Practice

Academy of Nutrition and Dietetics: Scope of Practice for the Registered Dietitian (2013)

- "Assess, recommend, and implement established and approved disease-specific and condition-specific protocol orders from the referring practitioner, executing interventions per protocol to meet individual nutrient and energy needs, including but not limited to prescribed diets; modification of food textures for dentition and individual preferences; nutritional supplements; dietary supplements" (p. S22)
- "Evaluate, educate, and counsel related to nutritional genomics, gene-diet and disease interactions, and food-drug, drug-nutrient, and supplement-drug-nutrient interactions" (p. S22)
- "RDs are skilled in functional and integrative medicine, nutritional genomics, whole foods, nutrition supplements and dietary supplements" (p. S24)
- "RDs evaluate dietary and sports supplements for safety, efficacy, and quality" (p. S24)



Academy Future-Focused Vision New Model of Differentiated Practice

eat right. Academy of Nutrition and Dietetics

A Future - Focused Vision for a New Model of Differentiated Entry-Level Nutrition and Dietetics Practice

Final 9/28/13

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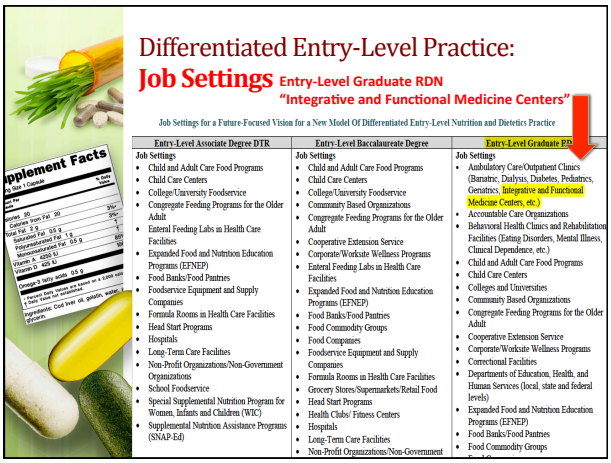
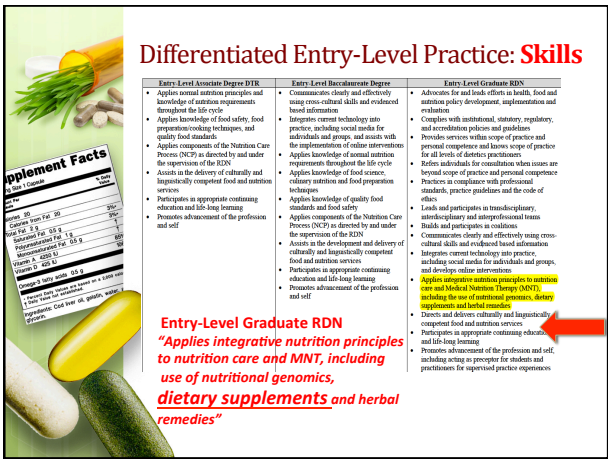
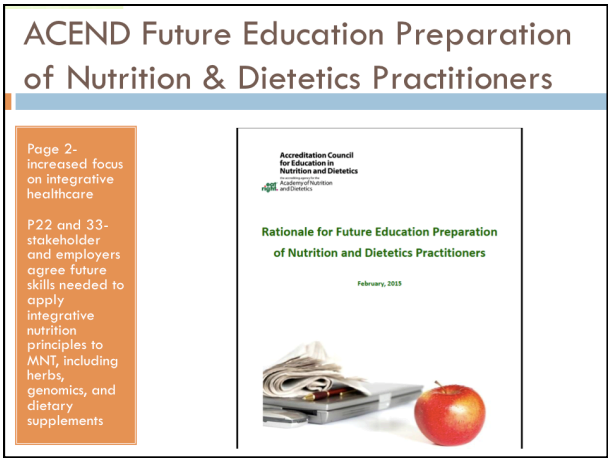
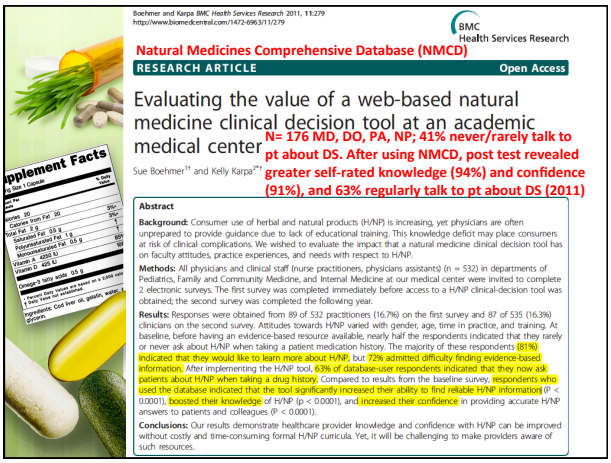

Differentiated Entry-Level Practice:
Job Settings Entry-Level Graduate RDN
"Integrative and Functional Medicine Centers"
Job Settings for a Future-Focused Vision for a New Model Of Differentiated Entry-Level Nutrition and Dietetics Practice
Entry-Level Associate Degree DTR
Job Settings
Child and Adult Care Food Programs
Child Care Centers
College/University Foodservice
Congregate Feeding Programs for the Older Adult
Enteral Feeding Labs in Health Care Facilities
Expanded Food and Nutrition Education Programs (EFNEP)
Food Banks/Food Pantries
Foodservice Equipment and Supply Companies
Formula Rooms in Health Care Facilities
Head Start Programs
Hospitals
Long-Term Care Facilities
Non-Profit Organizations/Non-Government Organizations
School Foodservice
Special Supplemental Nutrition Program for Women, Infants and Children (WIC)
Supplemental Nutrition Assistance Programs (SNAP-Ed)
Entry-Level Baccalaureate Degree
Job Settings
Child and Adult Care Food Programs
Child Care Centers
College/University Foodservice
Community Based Organizations
Congregate Feeding Programs for the Older Adult
Cooperative Extension Service
Corporate/Worksite Wellness Programs
Enteral Feeding Labs in Health Care Facilities
Expanded Food and Nutrition Education Programs (EFNEP)
Food Banks/Food Pantries
Food Companies
Foodservice Equipment and Supply Companies
Formula Rooms in Health Care Facilities
Grocery Stores/Supermarkets/Retail Food
Head Start Programs
Health Clubs/ Fitness Centers
Hospitals
Long-Term Care Facilities
Non-Profit Organizations/Non-Government
Entry-Level Graduate RDN
Job Settings
Ambulatory Care/Outpatient Clinics (Bariatrics, Dialysis, Diabetes, Pediatrics, Geriatrics, Integrative and Functional Medicine Centers, etc.)
Accountable Care Organizations
Behavioral Health Clinics and Rehabilitation Facilities (Eating Disorders, Mental Illness, Clinical Dependence, etc.)
Child and Adult Care Food Programs
Child Care Centers
Colleges and Universities
Community Based Organizations
Congregate Feeding Programs for the Older Adult
Cooperative Extension Service
Corporate/Worksite Wellness Programs
Correctional Facilities
Departments of Education, Health, and Human Services (local, state and federal levels)
Expanded Food and Nutrition Education Programs (EFNEP)
Food Banks/Food Pantries
Food Commodity Groups


Differentiated Entry-Level Practice: Skills
Entry-Level Associate Degree DTR
Applies normal nutrition principles and knowledge of nutrition requirements throughout the life cycle
Applies knowledge of food safety, food preparation/cooking techniques, and quality food standards
Applies components of the Nutrition Care Process (NCP) as directed by and under the supervision of the RDN
Assists in the delivery of culturally and linguistically competent food and nutrition services
Participates in appropriate continuing education and life-long learning
Promotes advancement of the profession and self
Entry-Level Baccalaureate Degree
Communicates clearly and effectively using cross-cultural skills and evidenced based information
Integrates current technology into practice, including social media for individuals and groups, and assists with the implementation of online interventions
Applies knowledge of normal nutrition requirements throughout the life cycle
Applies knowledge of food science, culinary nutrition and food preparation techniques
Applies knowledge of quality food standards and food safety
Applies components of the Nutrition Care Process (NCP) as directed by and under the supervision of the RDN
Assists in the development and delivery of culturally and linguistically competent food and nutrition services
Participates in appropriate continuing education and life-long learning
Promotes advancement of the profession and self
Entry-Level Graduate RDN
Advocates for and leads efforts in health, food and nutrition policy development, implementation and evaluation
Complies with institutional, statutory, regulatory, and accreditation policies and guidelines
Provides services within scope of practice and personal competence and knows scope of practice for all levels of dietetics practitioners
Refers individuals for consultation when issues are beyond scope of practice and personal competence
Practices in compliance with professional standards, practice guidelines and the code of ethics
Leads and participates in transdisciplinary, interdisciplinary and interprofessional teams
Builds and participates in coalitions
Communicates clearly and effectively using cross-cultural skills and evidenced based information
Integrates current technology into practice, including social media for individuals and groups, and develops online interventions
Applies integrative nutrition principles to nutrition care and Medical Nutrition Therapy (MNT), including the use of nutritional genomics, dietary supplements and herbal remedies
Directs and delivers culturally and linguistically competent food and nutrition services
Participates in appropriate continuing education and life-long learning
Promotes advancement of the profession and self, including acting as preceptor for students and practitioners for supervised practice experiences
Entry-Level Graduate RDN
"Applies integrative nutrition principles to nutrition care and MNT, including use of nutritional genomics, dietary supplements and herbal remedies"


ACEND Future Education Preparation of Nutrition & Dietetics Practitioners
Page 2- increased focus on integrative healthcare
P22 and 33- stakeholder and employers agree future skills needed to apply integrative nutrition principles to MNT, including herbs, genomics, and dietary supplements
Accreditation Council for Education in Nutrition and Dietetics
Academy of Nutrition and Dietetics
Rationale for Future Education Preparation of Nutrition and Dietetics Practitioners
February, 2015


Etiology-Driven Disease-Specific Dietary Supplement Use



Boehmer and Karpa *BMC Health Services Research* 2011, 11:279
http://www.biomedcentral.com/1472-6963/11/279

BMC Health Services Research

Natural Medicines Comprehensive Database (NMCD)

RESEARCH ARTICLE Open Access

Evaluating the value of a web-based natural medicine clinical decision tool at an academic medical center

N= 176 MD, DO, PA, NP; 41% never/rarely talk to pt about DS. After using NMCD, post test revealed greater self-rated knowledge (94%) and confidence (91%), and 63% regularly talk to pt about DS (2011)

Sue Boehmer[1†] and Kelly Karpa[2*†]

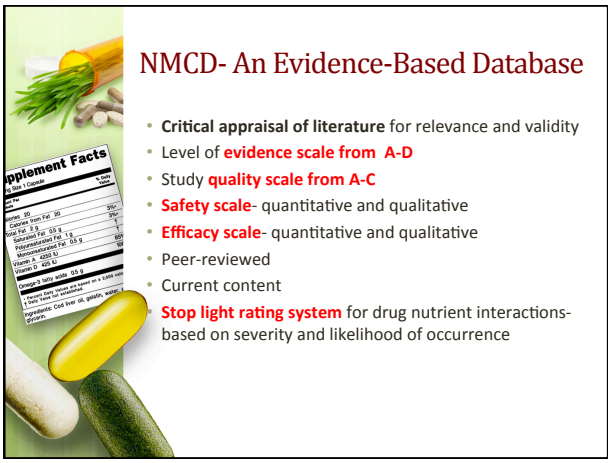
Abstract

Background: Consumer use of herbal and natural products (H/NP) is increasing, yet physicians are often unprepared to provide guidance due to lack of educational training. This knowledge deficit may place consumers at risk of clinical complications. We wished to evaluate the impact that a natural medicine clinical decision tool has on faculty attitudes, practice experiences, and needs with respect to H/NP.

Methods: All physicians and clinical staff (nurse practitioners, physicians assistants) (n = 532) in departments of Pediatrics, Family and Community Medicine, and Internal Medicine at our medical center were invited to complete 2 electronic surveys. The first survey was completed immediately before access to a H/NP clinical-decision tool was obtained; the second survey was completed the following year.

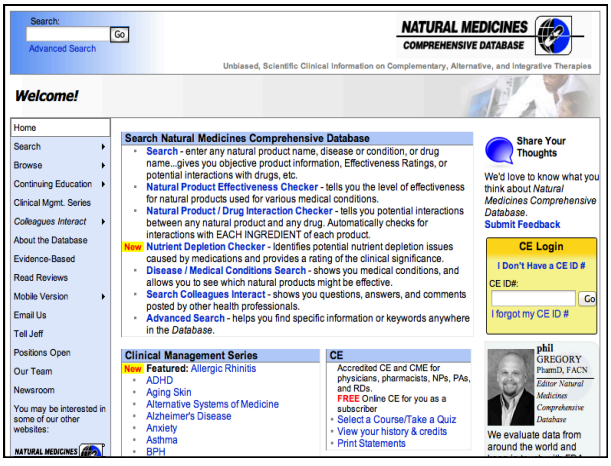
Results: Responses were obtained from 89 of 532 practitioners (16.7%) on the first survey and 87 of 535 (16.3%) clinicians on the second survey. Attitudes towards H/NP varied with gender, age, time in practice, and training. At baseline, before having an evidence-based resource available, nearly half the respondents indicated that they rarely or never ask about H/NP when taking a patient medication history. The majority of these respondents (81%) indicated that they would like to learn more about H/NP, but 72% admitted difficulty finding evidence-based information. After implementing the H/NP tool, 63% of database-user respondents indicated that they now ask patients about H/NP when taking a drug history. Compared to results from the baseline survey, respondents who used the database indicated that the tool significantly increased their ability to find reliable H/NP information ($P < 0.0001$), boosted their knowledge of H/NP ($p < 0.0001$), and increased their confidence in providing accurate H/NP answers to patients and colleagues ($P < 0.0001$).

Conclusions: Our results demonstrate healthcare provider knowledge and confidence with H/NP can be improved without costly and time-consuming formal H/NP curricula. Yet, it will be challenging to make providers aware of such resources.



NMCD- An Evidence-Based Database

- **Critical appraisal of literature** for relevance and validity
- Level of **evidence scale from A-D**
- Study **quality scale from A-C**
- **Safety scale**- quantitative and qualitative
- **Efficacy scale**- quantitative and qualitative
- Peer-reviewed
- Current content
- **Stop light rating system** for drug nutrient interactions- based on severity and likelihood of occurrence



Search Natural Medicines Comprehensive Database

- **Search** - enter any natural product name, disease or condition, or drug name...gives you objective product information, Effectiveness Ratings, or potential interactions with drugs, etc.
- **Natural Product Effectiveness Checker** - tells you the level of effectiveness for natural products used for various medical conditions.
- **Natural Product / Drug Interaction Checker** - tells you potential interactions between any natural product and any drug. Automatically checks for interactions with EACH INGREDIENT of each product.
- **Nutrient Depletion Checker** - Identifies potential nutrient depletion issues caused by medications and provides a rating of the clinical significance.
- **Disease / Medical Conditions Search** - shows you medical conditions, and allows you to see which natural products might be effective.
- **Search Colleagues Interact** - shows you questions, answers, and comments posted by other health professionals.
- **Advanced Search** - helps you find specific information or keywords anywhere in the *Database*.

Natural Product Search:

Natural Product Names that BEGIN with "SAMe":

- **SAMe**

Full Monograph	Interactions with Drugs	Also Known As
Safety	Interactions with Herbs	People Use This For
Effectiveness	Interactions with Food	Editor's Comments
Adverse Reactions	Interactions with Lab Tests	References
Dosage/Administration	Interactions with Diseases	
Mechanism of Action		

Patient Education Handout: English | Spanish | French

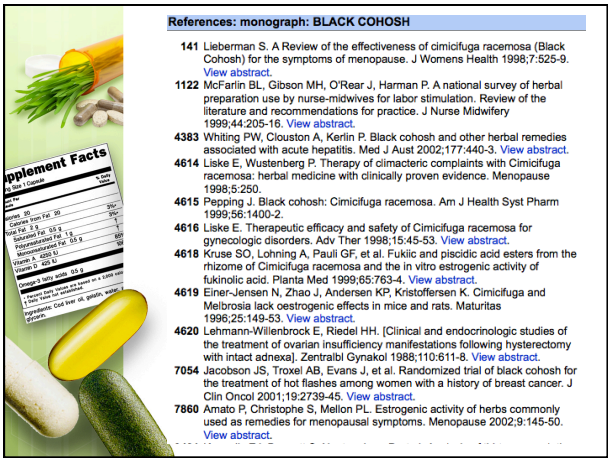
Also Known As:
Ademetionine, Adenosylmethionine, Adénosylméthionine, S-Adenosyl Methionine, S-Adénosyl Méthionine, S-Adenosyl-L-Methionine, S-Adénosyl-L-Méthionine, S-Adenosylmethionine, S-Adénosylméthionine, S-Adenosylmethionine Butanedisulfonate, S-Adenosylmethionine Tosylate, S-Adenosylmethionine Tosylate Disulfate, SAM, SAM-e, Sammy.

Scientific Name:
S-adenosyl-L-methionine.

People Use This For:
Orally, SAMe is used for depression, anxiety, heart disease, fibromyalgia, osteoarthritis, bursitis, tendonitis, chronic lower back pain, dementia, Alzheimer's disease, slowing the aging process, chronic fatigue syndrome (CFS), improving intellectual performance, liver disease, and Parkinson's disease. Other uses include premenstrual syndrome (PMS), premenstrual dysphoric disorder (PMDD), attention deficit-hyperactivity disorder (ADHD), multiple sclerosis, spinal cord injury, seizures, migraine headache, chronic lead poisoning, disorders of porphyrin, and bilirubin metabolism.
Intravenously, SAMe is used for treating depression, osteoarthritis, AIDS-related myelopathy, fibromyalgia, liver disease, cirrhosis, and intrahepatic cholestasis.
Intramuscularly, SAMe is injected for fibromyalgia, depression, and Alzheimer's disease.

Safety:
LIKELY SAFE ...when used orally, intravenously, or intramuscularly and appropriately. Serious toxicity has not been reported in multiple clinical studies involving more than 22,000 patients and lasting from a few days to 2 years (9189,5201,5202,5209,5219,5231,5232,12231,14840,17490).
CHILDREN: POSSIBLY SAFE ...when used orally or intravenously short-term. In small clinical trials, daily SAMe 75-1,000 mg daily was used with apparent safety for up to 30 days in children with hepatitis or intrahepatic cholestasis (20206,20456,20457,20458).
PREGNANCY: POSSIBLY SAFE ...when used intravenously short-term during the third trimester of pregnancy. In two small-scale trials, SAMe 800 mg daily was used intravenously for 14-20 days during the third trimester of pregnancy for intrahepatic cholestasis. No adverse effects in the mother or fetus were observed (5219,5231,5240). Large-scale trials are needed to confirm the safety of SAMe use in pregnancy. Use of SAMe in pregnancy should only be considered when benefits clearly outweigh the potential risks. There is insufficient reliable information available about the use of SAMe at higher doses, for extended periods of time, or during the earlier trimesters of pregnancy.
LACTATION: Insufficient reliable information available; avoid using.

Effectiveness:
LIKELY EFFECTIVE
Depression. Taking SAMe orally significantly improves symptoms of major depression. Several clinical studies show that taking SAMe is more effective than placebo and appears to be as effective as tricyclic antidepressants in trials lasting up to 42 days (2082,2083,5189,5190,5192,5195,5196,5231,9108,9109) (17490,20217,20218,20222,20223,20226,20467). However, some of these studies are limited by small numbers of patients, inconsistent diagnostic criteria, short treatment periods, and potentially flawed study designs (3562,5189,5231,9108).
Preliminary clinical research in patients who don't respond to conventional antidepressants suggests that taking SAMe titrated to an oral dose of 1,600 mg daily for 42 days does not seem to improve depression symptom scores from baseline in patients with major depressive disorder (20225). However, higher-quality clinical evidence suggests that adding a specific SAMe supplement (SAMe Complete 400 mg, Nature Made) 400 mg to 800 mg twice daily to conventional treatment significantly increases remission rates by about 14% after 6 weeks. About 7 patients need to be treated with SAMe for 6 weeks for one additional non-responding patient to have remission (17490).



References: monograph: BLACK COHOSH

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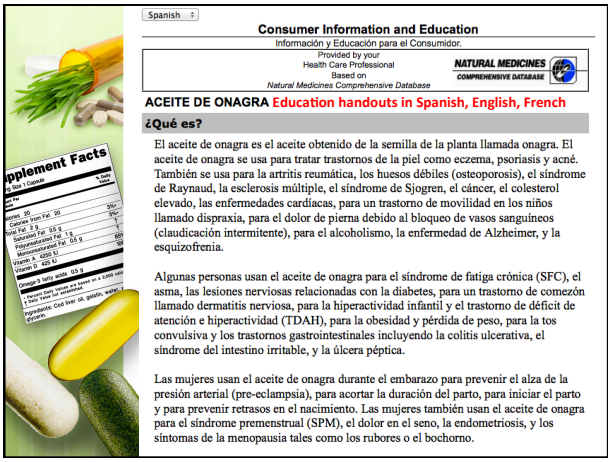


Spanish

Consumer Information and Education
Información y Educación para el Consumidor.
Provided by your Health Care Professional Based on *Natural Medicines Comprehensive Database*
NATURAL MEDICINES COMPREHENSIVE DATABASE

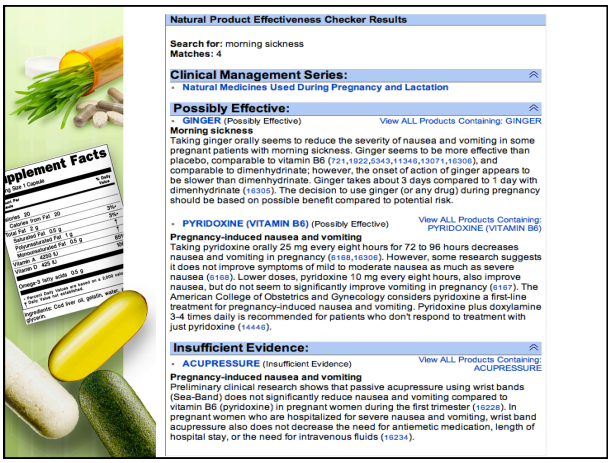
ACEITE DE ONAGRA Education handouts in Spanish, English, French

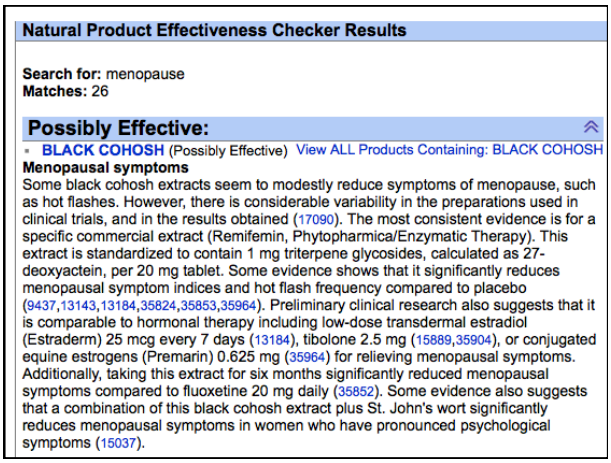
¿Qué es?

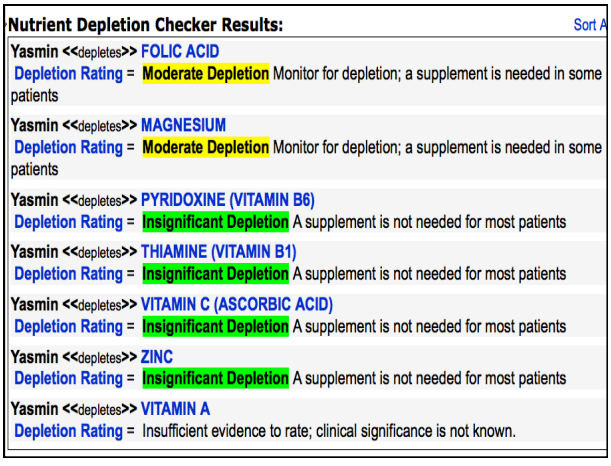
El aceite de onagra es el aceite obtenido de la semilla de la planta llamada onagra. El aceite de onagra se usa para tratar trastornos de la piel como eczema, psoriasis y acné. También se usa para la artritis reumática, los huesos débiles (osteoporosis), el síndrome de Raynaud, la esclerosis múltiple, el síndrome de Sjogren, el cáncer, el colesterol elevado, las enfermedades cardíacas, para un trastorno de movilidad en los niños llamado dispraxia, para el dolor de pierna debido al bloqueo de vasos sanguíneos (claudicación intermitente), para el alcoholismo, la enfermedad de Alzheimer, y la esquizofrenia.

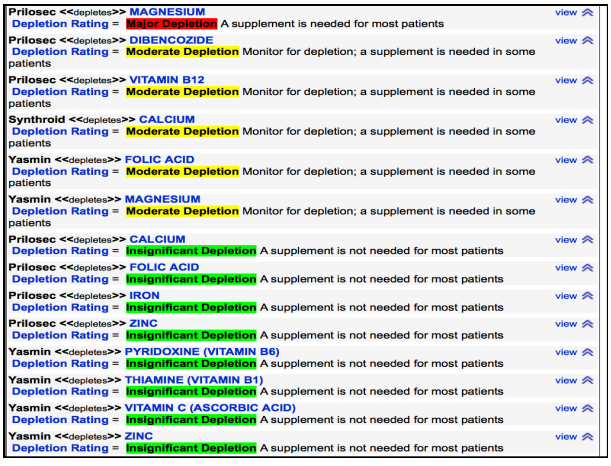
Algunas personas usan el aceite de onagra para el síndrome de fatiga crónica (SFC), el asma, las lesiones nerviosas relacionadas con la diabetes, para un trastorno de comezón llamado dermatitis nerviosa, para la hiperactividad infantil y el trastorno de déficit de atención e hiperactividad (TDAH), para la obesidad y pérdida de peso, para la tos convulsiva y los trastornos gastrointestinales incluyendo la colitis ulcerativa, el síndrome del intestino irritable, y la úlcera péptica.

Las mujeres usan el aceite de onagra durante el embarazo para prevenir el alza de la presión arterial (pre-eclampsia), para acortar la duración del parto, para iniciar el parto y para prevenir retrasos en el nacimiento. Las mujeres también usan el aceite de onagra para el síndrome premenstrual (SPM), el dolor en el seno, la endometriosis, y los síntomas de la menopausia tales como los rubores o el bochorno.


Natural Product Effectiveness Checker Results
Search for: morning sickness
Matches: 4
Clinical Management Series:
Natural Medicines Used During Pregnancy and Lactation
Possibly Effective:
GINGER (Possibly Effective)
View ALL Products Containing: GINGER
Morning sickness
Taking ginger orally seems to reduce the severity of nausea and vomiting in some pregnant patients with morning sickness. Ginger seems to be more effective than placebo, comparable to vitamin B6 (721,1922,5343,11348,13071,16306), and comparable to dimenhydrinate; however, the onset of action of ginger appears to be slower than dimenhydrinate. Ginger takes about 3 days compared to 1 day with dimenhydrinate (16305). The decision to use ginger (or any drug) during pregnancy should be based on possible benefit compared to potential risk.
PYRIDOXINE (VITAMIN B6) (Possibly Effective)
View ALL Products Containing: PYRIDOXINE (VITAMIN B6)
Pregnancy-induced nausea and vomiting
Taking pyridoxine orally 25 mg every eight hours for 72 to 96 hours decreases nausea and vomiting in pregnancy (6168,16306). However, some research suggests it does not improve symptoms of mild to moderate nausea as much as severe nausea (6168). Lower doses, pyridoxine 10 mg every eight hours, also improve nausea, but do not seem to significantly improve vomiting in pregnancy (6167). The American College of Obstetrics and Gynecology considers pyridoxine a first-line treatment for pregnancy-induced nausea and vomiting. Pyridoxine plus doxylamine 3-4 times daily is recommended for patients who don't respond to treatment with just pyridoxine (14446).
Insufficient Evidence:
ACUPRESSURE (Insufficient Evidence)
View ALL Products Containing: ACUPRESSURE
Pregnancy-induced nausea and vomiting
Preliminary clinical research shows that passive acupressure using wrist bands (Sea-Band) does not significantly reduce nausea and vomiting compared to vitamin B6 (pyridoxine) in pregnant women during the first trimester (16228). In pregnant women who are hospitalized for severe nausea and vomiting, wrist band acupressure also does not decrease the need for antiemetic medication, length of hospital stay, or the need for intravenous fluids (16234).


Natural Product Effectiveness Checker Results
Search for: menopause
Matches: 26
Possibly Effective:
BLACK COHOSH (Possibly Effective) View ALL Products Containing: BLACK COHOSH
Menopausal symptoms
Some black cohosh extracts seem to modestly reduce symptoms of menopause, such as hot flashes. However, there is considerable variability in the preparations used in clinical trials, and in the results obtained (17090). The most consistent evidence is for a specific commercial extract (Remifemin, Phytopharmica/Enzymatic Therapy). This extract is standardized to contain 1 mg triterpene glycosides, calculated as 27-deoxyactein, per 20 mg tablet. Some evidence shows that it significantly reduces menopausal symptom indices and hot flash frequency compared to placebo (9437,13143,13184,35824,35853,35964). Preliminary clinical research also suggests that it is comparable to hormonal therapy including low-dose transdermal estradiol (Estraderm) 25 mcg every 7 days (13184), tibolone 2.5 mg (15889,35904), or conjugated equine estrogens (Premarin) 0.625 mg (35964) for relieving menopausal symptoms. Additionally, taking this extract for six months significantly reduced menopausal symptoms compared to fluoxetine 20 mg daily (35852). Some evidence also suggests that a combination of this black cohosh extract plus St. John's wort significantly reduces menopausal symptoms in women who have pronounced psychological symptoms (15037).


Nutrient Depletion Checker Results:
Sort A
Yasmin <<depletes>> FOLIC ACID
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Yasmin <<depletes>> MAGNESIUM
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Yasmin <<depletes>> PYRIDOXINE (VITAMIN B6)
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> THIAMINE (VITAMIN B1)
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> VITAMIN C (ASCORBIC ACID)
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> ZINC
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> VITAMIN A
Depletion Rating = Insufficient evidence to rate; clinical significance is not known.


Prilosec <<depletes>> MAGNESIUM
view
Depletion Rating = Major Depletion A supplement is needed for most patients
Prilosec <<depletes>> DIBENCOZIDE
view
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Prilosec <<depletes>> VITAMIN B12
view
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Synthroid <<depletes>> CALCIUM
view
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Yasmin <<depletes>> FOLIC ACID
view
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Yasmin <<depletes>> MAGNESIUM
view
Depletion Rating = Moderate Depletion Monitor for depletion; a supplement is needed in some patients
Prilosec <<depletes>> CALCIUM
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Prilosec <<depletes>> FOLIC ACID
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Prilosec <<depletes>> IRON
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Prilosec <<depletes>> ZINC
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> PYRIDOXINE (VITAMIN B6)
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> THIAMINE (VITAMIN B1)
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> VITAMIN C (ASCORBIC ACID)
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients
Yasmin <<depletes>> ZINC
view
Depletion Rating = Insignificant Depletion A supplement is not needed for most patients

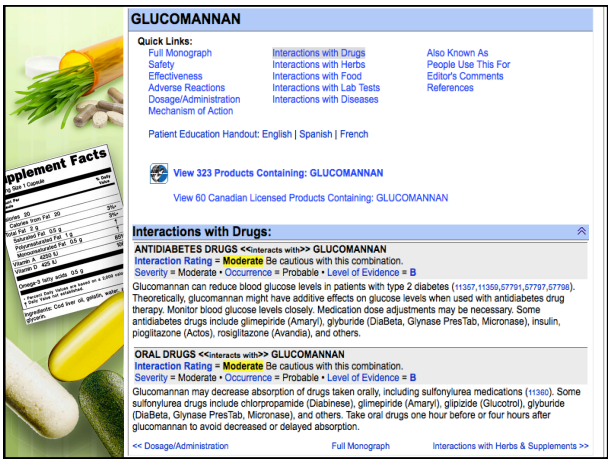
Level of Significance: Stop-Light Rating System Occurrence/Severity

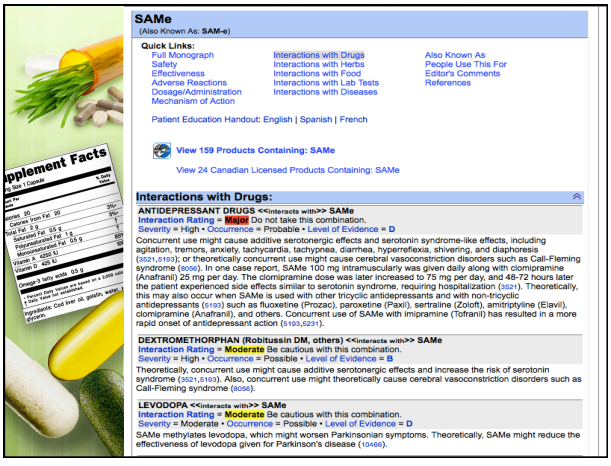
	Likely	Probable	Possible	Unlikely
High				
Moderate				
Mild				
Insignificant				

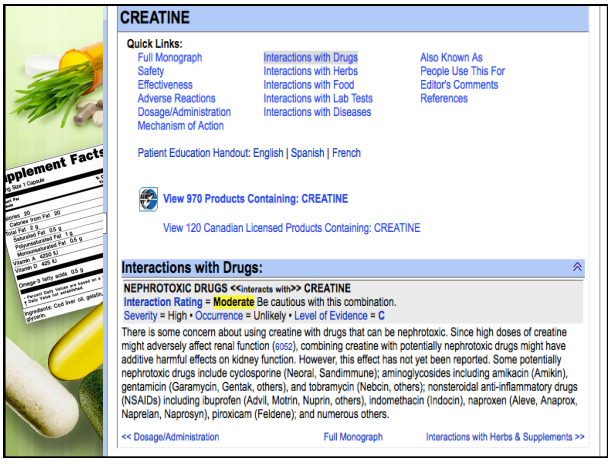
Major = Do not use combination; contraindicated; strongly discourage patients from using this combination; a serious adverse outcome could occur.

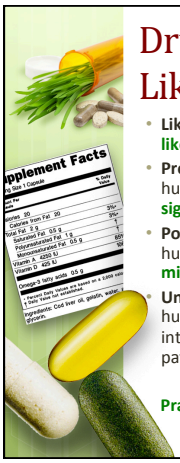
Moderate = Use cautiously or avoid combination; warn patients that a significant interaction or adverse outcome could occur.

Minor = Be aware that there is a chance of an interaction; advise patients to watch for warning signs of a potential interaction.









Drug Nutrient Interactions: Likelihood of Occurrence

- **Likely**- Clinical research indicates that this interaction is **likely to occur in most patients**.
- **Probable**- Clinical research or pharmacokinetic studies in humans suggests that this interaction **will occur in a significant portion of patients**.
- **Possible**- Clinical research, pharmacokinetic data in humans or animals, or in vitro research suggest that this **might occur** in some patients.
- **Unlikely**- Clinical research, pharmacokinetic data in humans or animals, or in vitro research suggest that this interaction **can occur, but is unlikely to occur** in many patients.

Practice Pearl: adapt this language to use with patients- likely, probable, possible, unlikely to occur.

Drug Nutrient Interactions: Severity

- **High** - Life threatening or severe impairment possible
- **Moderate**- Moderate impairment or significant discomfort possible.
- **Mild** - Mild impairment or mild discomfort possible.
- **Insignificant** - Drug levels may be affected, but a clinically significant interaction is not likely.

Practice Pearl: educate patients, and document education, about 'reasonably foreseeable side effects,' 'adverse events,' and adverse events reporting.

Clinical Management Series

Click on a course or report below to get practical evidence-based information on using natural medicines for specific conditions and other topics. Each course and report provides accredited continuing education (CE/CME) for physicians, pharmacists, NPs, PAs, and RDs, unless otherwise noted.

Clinical Management Series

- ADHD
- Aging Skin
- Allergic Rhinitis
- Alternative Systems of Medicine
- Alzheimer's Disease
- Anxiety
- Asthma
- BPH
- Breast Cancer
- Chronic Fatigue Syndrome
- Colds and Flu
- Colon Cancer
- Depression
- Diabetes
- Drug-Induced Nutrient Depletion
- Eye Disorders
- Fibromyalgia
- Headache
- Heart Failure
- HIV/AIDS
- Hyperlipidemia
- Hypertension
- IBD
- IBS
- Improving Athletic Performance
- Insomnia
- Menopause
- Nutrient Deficiencies
- Obesity
- Osteoarthritis
- Osteoporosis
- PMS
- Pain
- Pregnancy and Lactation
- Probiotics
- Protein Supplements
- UTI
- The Perioperative Use of Natural Medicines

Natural Medicines in the Clinical Management of Premenstrual Syndrome

Minerals/Vitamins | Supportive Treatment: Analgesics, NSAIDs, Diuretics | Antidepressants
Hormonal Agents | Miscellaneous | The Bottom Line
References

The cluster of symptoms called "premenstrual syndrome" received its official name in 1931, but its symptoms have been recognized since antiquity. Up to 85% of women are affected by PMS to varying degrees. It typically starts with development of menstruation in young women and tends to follow a consistent pattern until menopause.

Over 150 symptoms have been associated with PMS. The most common are irritability, agitation, headache, depression, breast tenderness, fluid retention, and weight gain. These symptoms typically show up in the second half of the menstrual cycle, about 7-10 days before the start of the next period.

Common Symptoms of Premenstrual Syndrome*

- Decreased interest in usual activities
- Depressed mood
- Difficulty concentrating

The editors
and its pub
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CME/CE a

CLICK HERE TO TAKE THIS QUIZ

Natural Medicines in the Clinical Management of Menopausal Symptoms

A hundred years ago menopause was not as big of a concern as it is today. In 1900, women typically lived to about age 50. The typical age of menopause was 51. Today, the typical age of menopause is still 51, but life expectancy is closer to 80 years. Women now spend much more time in menopause and post-menopause.

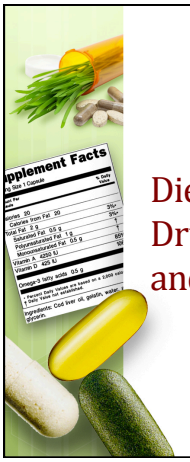
Premarin (conjugated estrogens) was introduced in 1942. But it didn't become popular until 1966 when Dr. Robert Wilson promoted it in his book Feminine Forever. The discovery of the connection between estrogen and uterine cancer resulted in the addition of a progestin in the 1980s, to help protect against endometrial hyperplasia. In the 1990s, long-term "hormone replacement therapy" (HRT) was being used by millions of women to prevent osteoporosis, cardiovascular disease, Alzheimer's disease, and other postmenopausal disorders.

This all changed in 2000. The results from the huge Women's Health Initiative (WHI) and the Heart and Estrogen/Progestin Replacement Study (HERS II) studies found conjugated estrogen plus medroxyprogesterone actually INCREASES the risk of myocardial infarction, stroke, venous thromboembolism, and breast cancer.[10958,10959,10960,10961] Since HERS II, additional findings have added concerns about an INCREASED risk for dementia and urinary incontinence.[10962,10963] Estrogen/progestin also does NOT seem to improve quality of life in older postmenopausal women without menopausal symptoms.[10964] Estrogen still has its place, but is no longer considered a drug for all reasons.

The editors of this activit and its publisher, Therapeutic Research Center, have no relevant financial interests related to the products or servic covered by this CME/CE activity.

Special Reports

- Alt Systems of Medicine
- Improving Athletic Performance
- Drug-Supplement Interactions (Non-CE Report)
- The Perioperative Use of Natural Medicines
- Selecting Supplements (Non-CE Report)



Dietary Supplements: Drug-Nutrient Interactions and Adverse Events

eat right.

RESEARCH

Research and Professional Briefs

N= 9,950; NHANES data- 34% of all US adults reported DS use with meds, most prevalent categories of meds were CVD meds and hormones (2014)

Concomitant Dietary Supplement and Prescription Medication Use Is Prevalent among US Adults with Doctor-Informed Medical Conditions☆

Emily K. Farina, PhD, RD; Krista G. Austin, PhD; Harris R. Lieberman, PhD

ARTICLE INFORMATION
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Prescription medications
Interactions
Chronic disease
Medical conditions

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Figure 1 available at www.andjnrl.org

2212-2672/$0.00
http://dx.doi.org/10.1016/j.jand.2014.01.016

ABSTRACT
Information on patterns of concomitant dietary supplement (DS) and prescription medication (PM) use among US adults is limited. Thus, the prevalence of concomitant DS and PM use as a function of doctor-informed medical conditions (DIMC) was determined in a cross-sectional, observational study of a nationally representative sample of noninstitutionalized, civilian adults aged ≥20 years in the United States (N=9,950) from the 2005-2008 National Health and Nutrition Examination Survey (NHANES). Data were weighted for the complex, multistage, probability sampling design. Approximately one third (34.3%) of all US adults reported concomitant DS and PM use (approximately one in three adults). The prevalence of use was significantly higher among those with vs without a DIMC (47.3% vs 17.3%). Adults with a DIMC were more than two and a half times more likely to concomitantly use DS and PM than adults without a DIMC, after adjustment for sex, age, education, and household income. Multivitamin plus other ingredient(s), followed by antacids and multivitamin plus botanical ingredient(s), were the most prevalent DS categories used with a PM among those with and without a DIMC. The most prevalent PM categories used with a DS were cardiovascular agents (among those with a DIMC) and hormones (among those without a DIMC). These findings demonstrate that presence of a DIMC may be a risk factor for concomitant DS and PM use among US adults. Multivitamins containing nonvitamin or mineral ingredients are more commonly used than standard multivitamins with PM by US adults. This may be an emerging trend that warrants further consideration.
J Acad Nutr Diet. 2014;■:■-■.

The Overlap of Dietary Supplement and Pharmaceutical Use in the MIDUS National Study

N= 3,876; 69% regularly used DS, 50% regularly use DS w/ meds
6% were high users meds and 9% were high users DS (2014)

David S. Kiefer,[1] Joe C. Chase,[1] Gayle D. Love,[2] and Bruce P. Barrett[1]

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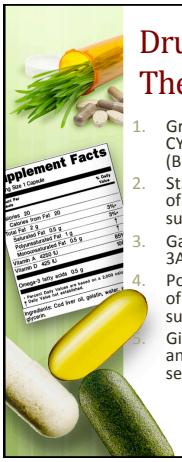
Received 15 December 2013; Revised 12 March 2014; Accepted 1 April 2014; Published 16 April 2014

Academic Editor: Zhong Zuo

Introduction. In the United States, dietary supplement (DS) use is common, often takes place outside of the purview of health care providers, and may involve DS in combination with pharmaceuticals. This situation has led to concerns about interactions between DS and pharmaceuticals, as well as the risks from polypharmacy and polysupplement use. *Methods.* We used data from the Midlife in the US study (MIDUS 2 Survey) to examine DS and prescription pharmaceutical use in 3876 study participants in order to determine the demographics of high-users (5 or more) of DS and pharmaceuticals and the presence of DS-pharmaceutical co-use. *Results.* Over 69% of study participants regularly used DS, 49.6% regularly used both DS and pharmaceuticals, and 6.3% and 8.7% were high-users of pharmaceuticals and DS, respectively. High-users of DS, pharmaceuticals, and either were more likely than the whole cohort to be female and of lower income. *Conclusions.* These findings corroborate those of other national studies with respect to the demographics of DS users but add new information about people at risk of DS-pharmaceutical interactions, not an insignificant proportion of the population examined by this dataset.



Drug Nutrient Interactions: The Top 10 and Level of Evidence

1. Grapefruit inhibitor of CYP450 3A4 substrates (B)
2. St. John's wort inducer of CYP450 3A4 substrates (B)
3. Garlic inducer of CYP450 3A4 substrates (B)
4. Pomegranate inhibitor of CYP450 3A4 substrates (D)
5. Ginkgo and anticonvulsants and seizure drugs (D)
6. Bitter orange and QT-interval prolonging drugs (D)
7. Calcium binding levothyroxine, antibiotics, quinolones, tetracycline, bisphosphonates (B)
8. Noni juice and ACE inhibitors (D)
9. Kava and hepatotoxic drugs (D)
10. Ginkgo and antiplatelet and anti-coagulant drugs (D)

Source: Natural Medicines Comprehensive Database, 2014

HEPATOLOGY
Official Journal of the American Association for the Study of Liver Diseases

Liver Injury and Regeneration

Liver injury from herbals and dietary supplements in the U.S. Drug-Induced Liver Injury Network

Victor J. Navarro[1,*], Huiman Barnhart[2], Herbert L. Bonkovsky[3], Timothy Davern[4], Robert J. Fontana[5], Lafaine Grant[6], K. Rajender Reddy[7], Leonard B. Seeff[1], Jose Serrano[8], Averell H. Sherker[9], Andrew Stu[10], Jayant Talwalkar[11], Maricruz Vega[1] and Raj Vuppalanchi[12]

Article first published online: 25 AUG 2014
DOI: 10.1002/hep.27317

Issue

Hepatology

Early View (Online Version of Record published before inclusion in an issue)

Liver injury caused by HDS increased from 7% to 20% during the study period.

Am score 152

Additional Information (Show All)

NIH National Center for Complementary and Alternative Medicine (NCCAM)

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NCCAM **research**blog

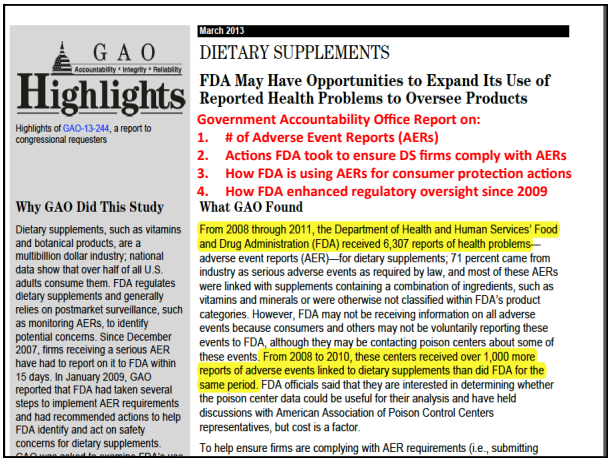
Seeking Applicants for Natural Product–Drug Interactions Center of Excellence

Craig Hopp, Ph.D.
Program Director
National Center for Complementary and Alternative Medicine

September 12, 2014

View Dr. Hopp's biographical sketch

In August 2013, I blogged about NCCAM's interest in the potential interactions of natural products with prescription and over-the-counter medications. Today, I'm happy to tell you that we'll hold a webinar for investigators on Tuesday, October 7, 2014, to discuss our funding opportunity announcement for the Center of Excellence for Natural Product Drug Interaction Research.



GAO
Accountability * Integrity * Reliability

Highlights

Highlights of GAO-13-244, a report to congressional requesters

March 2013

DIETARY SUPPLEMENTS

FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products

Government Accountability Office Report on:

1. **# of Adverse Event Reports (AERs)**
2. **Actions FDA took to ensure DS firms comply with AERs**
3. **How FDA is using AERs for consumer protection actions**
4. **How FDA enhanced regulatory oversight since 2009**

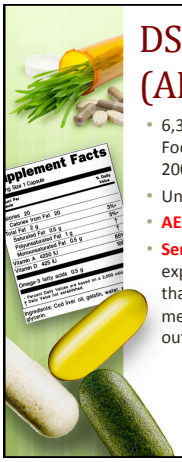
Why GAO Did This Study

Dietary supplements, such as vitamins and botanical products, are a multibillion dollar industry; national data show that over half of all U.S. adults consume them. FDA regulates dietary supplements and generally relies on postmarket surveillance, such as monitoring AERs, to identify potential concerns. Since December 2007, firms receiving a serious AER have had to report on it to FDA within 15 days. In January 2009, GAO reported that FDA had taken several steps to implement AER requirements and had recommended actions to help FDA identify and act on safety concerns for dietary supplements.

What GAO Found

From 2008 through 2011, the Department of Health and Human Services' Food and Drug Administration (FDA) received 6,307 reports of health problems—adverse event reports (AER)—for dietary supplements; 71 percent came from industry as serious adverse events as required by law, and most of these AERs were linked with supplements containing a combination of ingredients, such as vitamins and minerals or were otherwise not classified within FDA's product categories. However, FDA may not be receiving information on all adverse events because consumers and others may not be voluntarily reporting these events to FDA, although they may be contacting poison centers about some of these events. From 2008 to 2010, these centers received over 1,000 more reports of adverse events linked to dietary supplements than did FDA for the same period. FDA officials said that they are interested in determining whether the poison center data could be useful for their analysis and have held discussions with American Association of Poison Control Centers representatives, but cost is a factor.

To help ensure firms are complying with AER requirements (i.e., submitting



DS Adverse Events Reports (AERs)

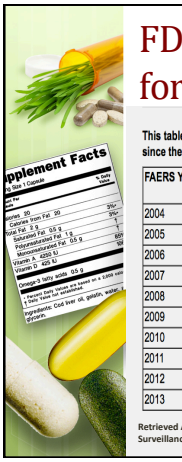
- 6,307 DS-related AERs were reported to FDA Center for Food Safety and Applied Nutrition (FDA CFSAN) from 2008-2011
- Under-reporting is likely, extent is unknown
- **AERs are categorized as mild, moderate, or serious**
- **Serious adverse events** 'result in death, life-threatening experience, in-patient hospitalization, or birth defect, or that require, based on reasonable medical judgment, a medical or surgical intervention to prevent these serious outcomes'

Government Accountability Office, March 2013. GAO-13-244 Dietary Supplements

DS Adverse Events Reports (AERs)

- **6,307 total DS AERs from 2008-2011**
  - 3,370 unspecified; serious
  - 1,836 required hospitalization
  - 1,272 resulted in serious injuries or illness
  - 512 resulted in life-threatening conditions
  - 92 deaths
  - 'Combination products' most frequent AERs
  - Vitamins 2nd most frequent AERs
  - Minerals 3rd most frequent AERs
- **2.7 million total prescription drug AERs from 2008-2011**

1. Government Accountability Office, March 2013. GAO-13-244 Dietary Supplements
2. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm

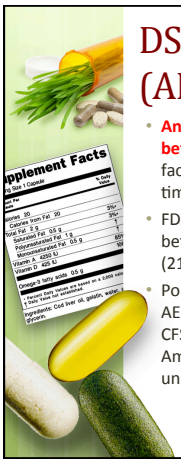


FDA Adverse Event Reports for Medications

This table represents the number of reports received by FDA and entered into FAERS by type of report since the year 2004 through 2013.

FAERS YEAR	Expedited	DIRECT	Non Expedited Entered	Total Entered	Non Expedited Received	Total Rcvd
2004	161,382	21,654	89,841	272,877	239,271	422,307
2005	212,140	25,311	84,486	321,937	225,183	462,634
2006	219,231	20,979	95,556	335,766	230,065	470,275
2007	230,000	23,035	110,407	363,442	228,206	481,241
2008	274,315	32,900	132,686	439,901	218,205	525,420
2009	330,441	34,172	126,192	490,805	216,264	580,877
2010	409,637	28,951	234,699	673,287	320,341	758,929
2011	499,576	28,064	255,362	783,002	346,745	874,385
2012	585,208	29,162	323,077	937,447	475,993	1,090,363
2013	643,293	28,501	406,235	1,078,029	506,512	1,178,306

Retrieved April 2015 from http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm



DS Adverse Events Reports (AERs)

- **An AER does not indicate a causal relationship between a DS and reported health problem**. Other factors to consider are other products taken at same time and preexisting health conditions
- FDA was only able to establish a '*certain*' relationship between the DS and reported health problem in 3% (212 of 6,307) of the AERs
- Poison control centers report 4,863 cases of DS-related AERs from 2008-2011, but cases are not sent to FDA CFSAN, and case 'overlap' between FDA CFSAN and American Association of Poison Control Centers is unknown

Government Accountability Office, March 2013.
GAO-13-244 Dietary Supplements

Natural Health Product–Drug Interactions: Evolving Responsibilities to Take Complementary and Alternative Medicine Into Account

Whose responsibility is it to inquire about DS use and advise on drug-nutrient interactions? (Canada, 2011)

AUTHORS: Joan Gilmour, LLB, JSD,[a] Christine Harrison, MA, PHD,[b] Leyla Asadi, MD,[c] Michael H. Cohen, JDA, MBA,[d] and Sunita Vohra, MD, MSc[e,f]

[a]Osgoode Hall Law School, York University, Toronto, Ontario, Canada; [b]Department of Bioethics, SickKids Hospital, Toronto, Ontario, Canada; Departments of [c]Medicine and [e]Pediatrics, Faculty of Medicine, University of Alberta, Edmonton, Alberta, Canada; [d]Fenton Nelson LLP, Los Angeles, California; and [f]CARE Program for Integrative Health & Healing, Stollery Children's Hospital, Edmonton, Alberta, Canada

KEY WORDS
complementary therapies, herb-drug interactions, legal liability, pediatrics

ABBREVIATIONS
NHP—natural health product
CAM—complementary and alternative medicine

www.pediatrics.org/cgi/doi/10.1542/peds.2010-2720C

doi:10.1542/peds.2010-2720C

Accepted for publication Mar 30, 2011

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: *The authors have indicated they have no financial relationships relevant to this article to disclose.*

abstract

Natural health products (NHPs) (known as dietary supplements in the United States) are a popular form of self-care, yet many patients do not disclose their use to clinicians. NHP-drug interactions are known to occur and can harm patients and affect the efficacy of conventional treatment. Using the example of an HIV-positive adolescent who had been responding well to antiretroviral therapy but then experienced a sudden unexplained deterioration in her condition, we review (1) clinicians' obligation to inquire about complementary and alternative medicine (CAM) use when assessing, treating, and monitoring patients, (2) how clinicians' duty to warn about risks associated with treatment has evolved and expanded, and (3) patients' and parents' responsibility to disclose CAM use. It also addresses the responsibility of hospitals and health facilities to ensure that the reality of widespread CAM/NHP use is taken into account in patient care to effectively protect patients from harm. *Pediatrics* 2011;128:S155–S160

SUPPLEMENT ARTICLE

Pediatric Use of Complementary and Alternative Medicine: Legal, Ethical, and Clinical Issues in Decision-Making

Who are the appropriate clinical decision-makers? (Canada, 2011)

AUTHORS: Joan Gilmour, LLB, JSD,[a] Christine Harrison, MA, PHD,[b] Michael H. Cohen, JDA, MBA,[c] and Sunita Vohra, MD, MSc[d,e]

[a]Osgoode Hall Law School, York University, Toronto, Ontario, Canada; [b]Department of Bioethics, SickKids Hospital, Toronto, Ontario, Canada; [c]Fenton Nelson LLP, Los Angeles, California; [d]CARE Program for Integrative Health & Healing, Stollery Children's Hospital, Edmonton, Alberta, Canada; and [e]Department of Pediatrics, Faculty of Medicine, University of Alberta, Alberta, Canada

KEY WORDS
complementary therapies, clinical ethics, evidence-based practice, jurisprudence, pediatrics

ABBREVIATION
CAM—complementary and alternative medicine

www.pediatrics.org/cgi/doi/10.1542/peds.2010-2720B

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Accepted for publication Mar 30, 2011

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: *The authors have indicated they have no financial relationships relevant to this article to disclose.*

abstract

In this article we introduce a series of 8 case scenarios and commentaries and explore the complex legal, ethical, and clinical concerns that arise when pediatric patients and their parents or health care providers use or are interested in using complementary and alternative medicine (CAM). People around the world rely on CAM, so similar issues face clinicians in many countries. In law, few cases have dealt with CAM use. The few that have apply the same general legal principles used in cases that involved conventional care while taking into account considerations unique to CAM. In ethics, as with conventional care, the issues surrounding pediatric CAM use usually involve questions about who the appropriate decision-makers are, on what ethical principles should clinical decision-making rely, and what obligations arise on the part of physicians and other health care providers. Clinical decision-making is made more complex by the relatively limited research on the efficacy and safety of CAM compared with conventional medicine, especially in children, which requires clinicians to make decisions under conditions of uncertainty. The clinical scenarios presented focus on patients who represent a range of ages, clinical conditions, and settings. They act as anchors to explore particular CAM policy issues and illustrate the application of and shortcomings in existing guidance and intervention principles. Although the focus on a pediatric population

Dietary Supplement Resources

American Botanical Council
http://abc.herbalgram.org/site/PageServer

Computer Access to Research on Dietary Supplements (CARDS) Database http://ods.od.nih.gov/Research/CARDS_Database.aspx

Consumer Labs www.consumerlab.com/

Council for Responsible Nutrition www.crnusa.org/

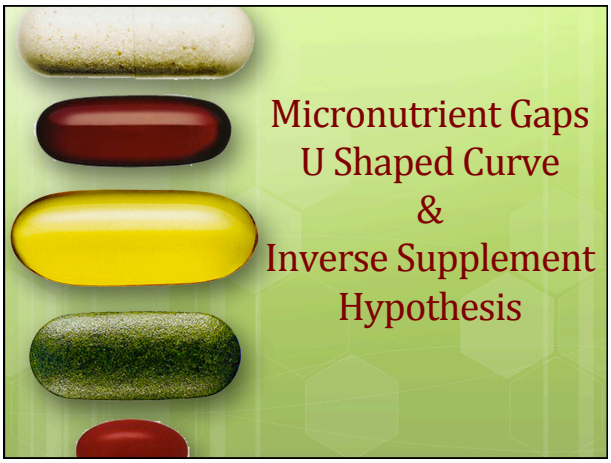
Food, Drug & Herbal Interactions www.epocrates.com/

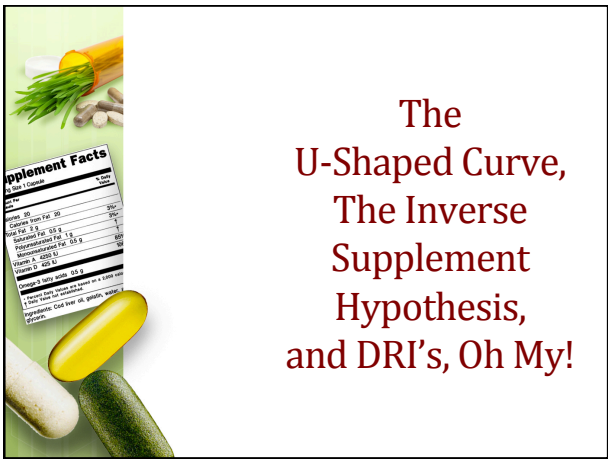
Herb Research Foundation www.herbs.org/

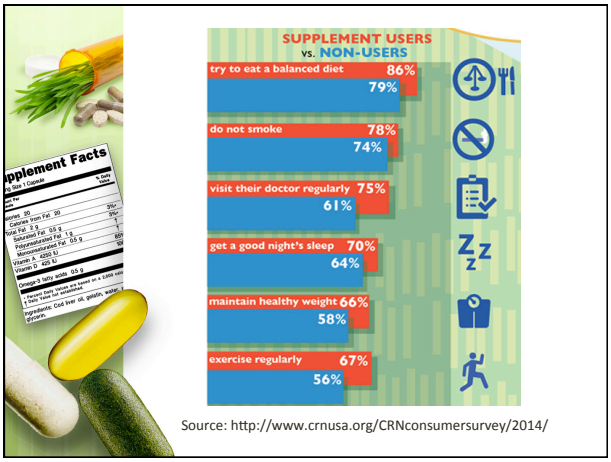
National Library of Science Dietary Supplements Labels Database http://www.dsld.nlm.nih.gov/dsld/

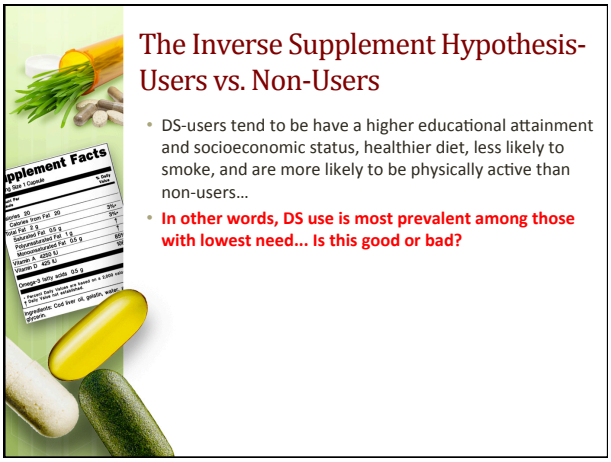
Natural Medicines Comprehensive Database/Natural Standard www.naturaldatabase.com/

NIH Office of Dietary Supplements www.ods.od.nih.gov/


Micronutrient Gaps
U Shaped Curve
&
Inverse Supplement
Hypothesis

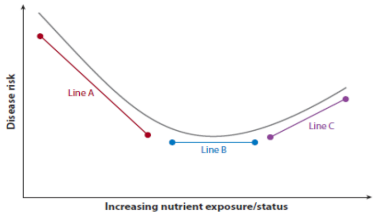

The
U-Shaped Curve,
The Inverse
Supplement
Hypothesis,
and DRI's, Oh My!


SUPPLEMENT USERS
vs. NON-USERS
try to eat a balanced diet 86%
79%
do not smoke 78%
74%
visit their doctor regularly 75%
61%
get a good night's sleep 70%
64%
maintain healthy weight 66%
58%
exercise regularly 67%
56%
Source: http://www.crnusa.org/CRNconsumersurvey/2014/


The Inverse Supplement Hypothesis-
Users vs. Non-Users
DS-users tend to be have a higher educational attainment and socioeconomic status, healthier diet, less likely to smoke, and are more likely to be physically active than non-users…
In other words, DS use is most prevalent among those with lowest need… Is this good or bad?

Micronutrient U-Shaped Curve: Too Much of A Good Thing?

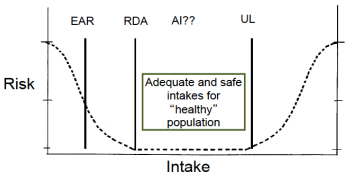
Hypothetical effect of a nutrient intervention on disease risk (Y axis) depending on baseline nutritional status (X axis). Source: Mayne et al., Annual Rev Nutr 2012



Key Point: more prospective long term trials with primary disease endpoints are needed to explore U-shaped curves, micronutrient upper limits (UL) and toxicity.

Micronutrient U-Shaped Curve, DRI's, & Disease Risk

Dietary Reference Intakes (DRIs)



Estimated Average Requirement (EAR) meets the needs of 50% of healthy population

Recommended Dietary Allowance (RDA) meets the needs of 97.5% of healthy population

Adequate Intake (AI) keeps people in apparently good health when RDA can't be determined

Tolerable Upper Intake Level (UL) > levels increase potential risk for harm

Practice Pearl: Screen long term DS-users for risk of toxicity, test as indicated

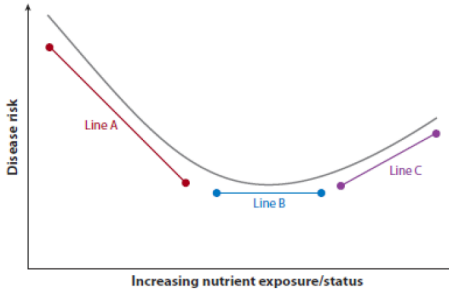
Source: FNB, IOM, NAS

US Diet Micronutrient Gaps

- Calcium
- Vitamin D
- Magnesium
- Omega-3 fatty acids
- Potassium
- Fiber
- Vitamin E
- Vitamin B12

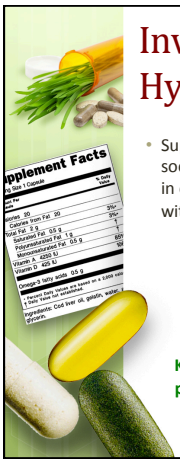
Source: NIH Office of Dietary Supplements: *Vulnerable Groups, Shortfall Nutrients, and Micronutrient Basics*

Hypothetical effect of a nutrient intervention on disease risk (Y axis) depending on baseline nutritional status (X axis). Source: Mayne et al., Annual Rev Nutr 2012



Yale CANCER CENTER

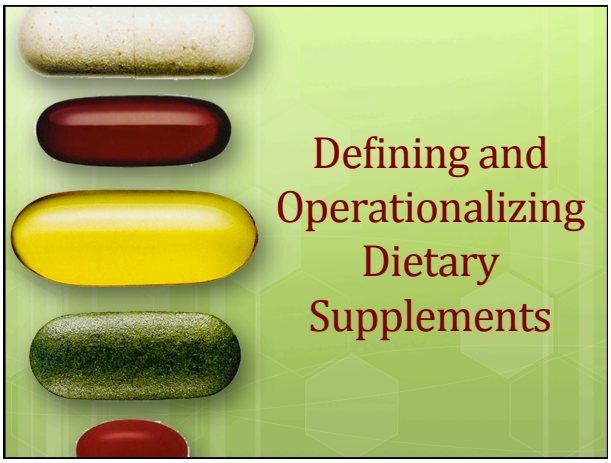
Yale SCHOOL OF PUBLIC HEALTH



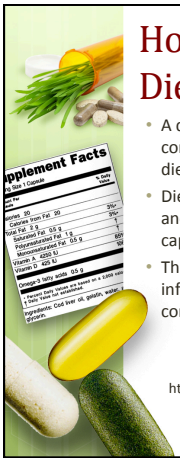
Inverse Supplement Hypothesis

- Supplement users tend to be have a higher socioeconomic status, healthier diet, healthier lifestyle- in other words, DS use is most prevalent among those with lowest need

Key Point: more prospective long term trials with primary disease endpoints are needed to explore U shaped curves, micronutrient UL and toxicity.



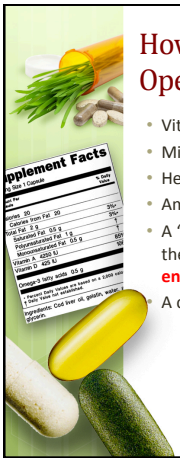
Defining and Operationalizing Dietary Supplements



How Does FDA Define Dietary Supplement?

- A dietary supplement is a product **taken by mouth** that contains a **dietary ingredient** intended to supplement the diet
- Dietary supplements can also be extracts or concentrates, and may be found in **many forms** such as tablets, capsules, softgels, gelcaps, liquids or powders
- They can also be in other forms such as a bar, but label information must not represent the product as a conventional food

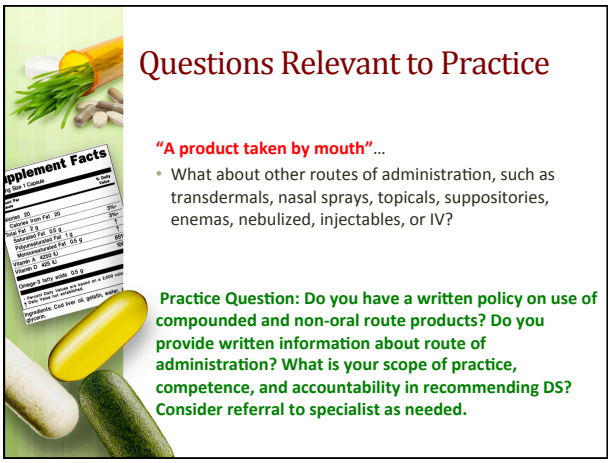
http://www.fda.gov/food/dietarysupplements/ accessed July 2014



How Does FDA Define and Operationalize Dietary Ingredients?

- Vitamins
- Minerals
- Herbs or other botanicals
- Amino acids
- A 'dietary substance' for use by people to supplement the diet by increasing the total dietary intake (**e.g., enzymes or tissues from organs or glands**)
- A concentrate, metabolite, constituent or extract

http://www.fda.gov/food/dietarysupplements/ accessed October 2015



Questions Relevant to Practice

"A product taken by mouth"…

- What about other routes of administration, such as transdermals, nasal sprays, topicals, suppositories, enemas, nebulized, injectables, or IV?

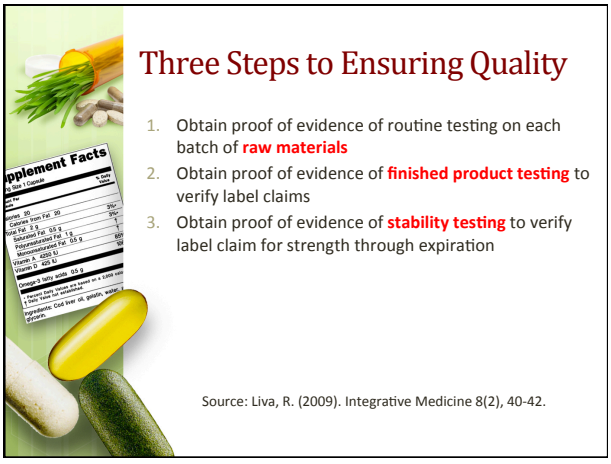
Practice Question: Do you have a written policy on use of compounded and non-oral route products? Do you provide written information about route of administration? What is your scope of practice, competence, and accountability in recommending DS? Consider referral to specialist as needed.

Dietary Supplements Quality, Purity & Identity

Identity, Strength, & Purity for Raw Materials and Finished Product

- Identity: verifies authenticity
- Strength: verifies potency
- Purity: verifies adulterant and contaminant levels

Source: Liva, R. (2009). Integrative Medicine 8(2), 40-42.



Three Steps to Ensuring Quality

1. Obtain proof of evidence of routine testing on each batch of **raw materials**
2. Obtain proof of evidence of **finished product testing** to verify label claims
3. Obtain proof of evidence of **stability testing** to verify label claim for strength through expiration

Source: Liva, R. (2009). Integrative Medicine 8(2), 40-42.

Typical Testing Profile for Raw Materials

- Strength assay
- Heavy metals, pesticide residue, solvent residue
- Aflatoxins, microbial content, rancidity markers, and yeast/mold content
- GMOs and industrial pollutants

Source: Liva, R. (2009). Integrative Medicine 8(2), 40-42.

Milk Thistle GC/MS- Solvent Contamination with Benzene (Class I), Hexanes (Class II) Heptanes &Pentanes (Class III)

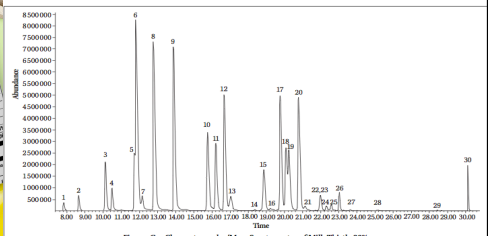


Figure. Gas Chromatography/Mass Spectrometry of Milk Thistle 80%

Note: Manufacturer reported as "ethanol and water extract"

THE *IMCJ* SUPPLEMENT QUALITY AUDIT FORM

Source: *Integrative Medicine Clinician's Journal*, 2009 8(3), 51-55.

TO: _____

RE: Program of Vendor Quality Certification and "The *IMCJ* Supplement Quality Audit Form"

The companies that supply us with dietary supplements (our vendors) are the essence of our success. Our business cannot exist without quality materials and services. Therefore, to ensure the quality of the products we provide our patients (capsules, tablets, tinctures, powders, etc), we have embarked on a Program of Vendor Quality Certification designed to foster working partnerships with all of our valued vendors of dietary supplements. We feel that developing an open, trusting, cooperative relationship with each company is a prerequisite to selling any of your products.

Vendor certification is an important component of a Total Quality Management System. It (1) assures that a vendor's product is produced, packaged, and shipped under controlled processes that result in consistent conformance to our requirements and (2) supports the concept of "quality at the source" by placing responsibility for such quality on you, the vendor.

As a medical practice, we feel very strongly about the importance and need for certification and have included it as a major cornerstone of our business philosophy. Thus, we seek to identify and do business with natural product suppliers and/or manufacturers that meet or exceed the following objectives.

OBJECTIVES:

We are seeking vendors who

1. are interested in making certification a standard part of doing business;
2. are committed to partnering with us;
3. develop internal programs to assure consistent quality, good communication, timely delivery, and best overall cost;
4. have in place or are willing to put in place a documented quality system. This would include
   a) adhering to all the applicable US Food and Drug Administration (FDA) regulatory requirements as put forth in its guidelines for current Good Manufacturing Practices (cGMPs) for the manufacture of nutritional supplements;
   b) having or being willing to create a comprehensive quality control testing program that assures raw material and finished products are fit for use—eg, they are authentic, meet label claims for strength and stability through the expiration dating period, and have maximum freedom from contamination; and
   c) having the ability to provide legitimate proof that your products meet set quality standards.

To this end, please answer questions on "The *IMCJ* Supplement-Quality Audit Form" below and return your completed audit to us.

In an effort to protect your intellectual property and confidentiality, you may provide only the first and last sheets for audit reports, standard operating procedures, and other multipage forms as proof of proper documentation.

We request that you return this form **within 1 month** of the fax date.

We greatly appreciate your time and effort.

Clinician/Practice Name: _____
Address: _____
_____
E-mail: _____
Phone: _____ Fax: _____

CGMP & QUALITY PROCEDURES

Check 1 column or circle 1 answer for each.

Source: *Integrative Medicine Clinician's Journal*, 2009 8(3), 51-55.	*Y	N	N/A
1. Does your company have a Quality Control Unit?			
2. Does the quality unit have the authority to approve/reject the following:			
a. Procedures	a	a	a
b. Specifications	b	b	b
c. Test methods and results	c	c	c
d. Instrument/control calibrations	d	d	d
e. Raw ingredients/components	e	e	e
f. Finished ingredients	f	f	f
g. Packaging materials	g	g	g
h. Labels	h	h	h
i. Processing records	i	i	i
j. Forms (ie, batch production records, inventory control records, performance logs, etc)	j	j	j
k. Reprocessing operations	k	k	k
3. Which current Good Manufacturing Practices (cGMPs) do you follow? a. Food cGMPs b. FDA cGMPs for Dietary Supplements c. We have no cGMP system	a b c		
4. Is there a plant-wide internal cGMP audit program? a. If yes, how often do you audit? (Please circle answer.) Yearly Every 2 yrs Every 5 yrs Other: _____ » If yes, please attach a copy of your internal audit form.	—	—	—

RAW MATERIAL QUALITY

Check 1 column or circle 1 answer for each.

Source: *Integrative Medicine Clinician's Journal*, 2009 8(3), 51-55.

	*Y	N	N/A
10. Do you accept a certificate of analysis in lieu of independent testing of raw materials? » If yes, please provide a written, detailed rationale for how you control the quality of your raw materials at the time of receipt.			
11. Do you have an in-house QC lab? •If yes, please list the name, phone extension, fax, and email of supervisor: _____ •If yes, how many analysts by level of education are in the lab? GED ___ BS ___ MS ___ PhD ___	—	—	—
12. If you use a contract QC lab(s), is it audited by any of the following a. Company personnel b. A third party c. Not audited •If audited, how often? (Please circle answer).) Yearly Every 2 yrs Every 5 yrs Other: _____ » If not audited, please provide a written, detailed rationale for how you control the quality of your raw materials.	a b c		

13B. When doing in-house or independent testing of NON-BOTANICAL raw materials are they tested for the following? (Please provide 2 examples of test data for each item "a" to "e.")

a. Identity (to authenticate material or botanical genus and species) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	a	a
b. Potency (if a potency claim exists) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	b	b
c. Heavy Metals (lead, mercury, cadmium, arsenic) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	c	c
d. Microbiology Profile (bacteria, yeast, and mold) • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	d	d
e. Chemical Solvent Residue • If yes, are SOME or ALL materials tested? (Circle answer) • If yes, how often? (Circle one) 1. Each batch received 2. Skip-lot testing (If so, how often?): _____ 3. Other (If so, how often): _____	e	e
» Note: If your company either does not test 1 or more of the items listed in "a" to "g" and/or does not test *every* batch of received material for these parameters, please provide a detailed rationale proving how omitting such testing is not missing a quality parameter.		

Source: *Integrative Medicine Clinician's Journal*, 2009 8(3), 51-55.

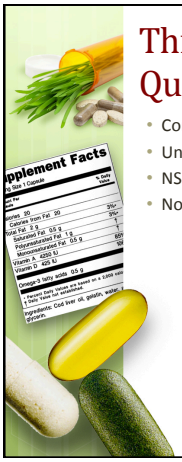
FINISHED PRODUCT QUALITY

Check 1 column or circle 1 answer for each.

Source: *Integrative Medicine Clinician's Journal*, 2009 8(3), 51-55.

	*Y	N	N/A
16. Do you put expiration/"use by" dates on your products? » If no, please provide a rationale for how you prove you meet label claim.	—	—	
17. Are your finished products tested for label-claim potency prior to release for sale? » If yes, please provide full test data for 3 different products. » If no, please provide a rationale for how you prove you meet label claim.	—	—	
18. Do you perform label-claim potency testing (stability testing) to verify that the product meets label claim throughout the expiration dating/use by period? » If yes, please provide stability potency assays on 3 different finished product batches that were tested to verify the expiration date claim. » If no, please provide a detailed rationale for how you prove that you have met the label claim through the dated period.	—	—	
19. Are any major food allergens (eg, milk, eggs, fish, shellfish, nuts, wheat, peanuts, and soybeans) produced, handled, or stored at or near this facility? » If yes, please describe what precautions are taken to avoid cross-contamination. » If yes, please describe what cautionary language is placed on product or material labels to warn of the potential presence of allergens.	—	—	
20. Is the production for any finished goods subcontracted? » If yes, please explain how you ascertain quality control (eg, identity, strength, no adulteration or contamination) for the other facility/facilities?	—	—	

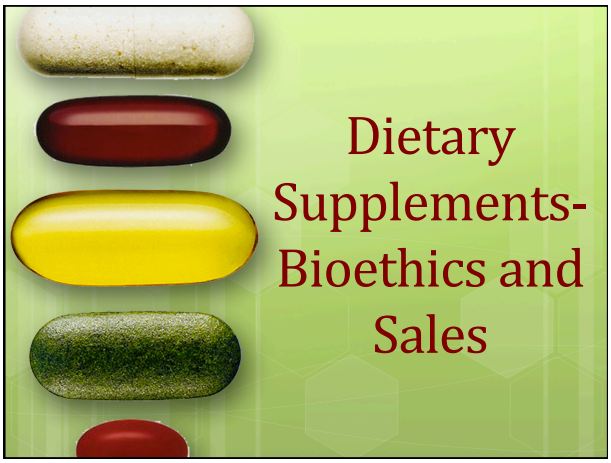
*Y = yes, N = no, N/A = not applicable

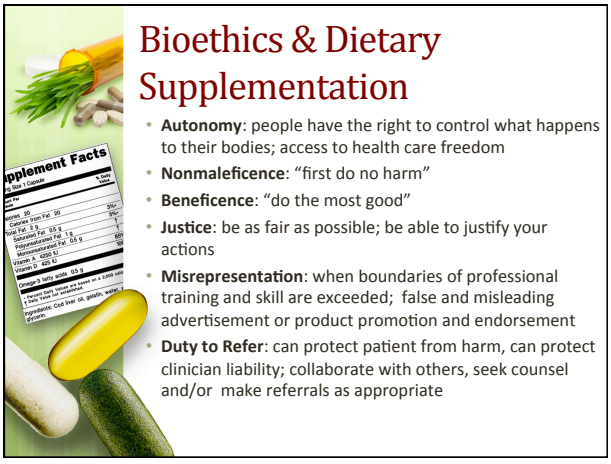


Third Party Verification of Quality, Purity, Identity

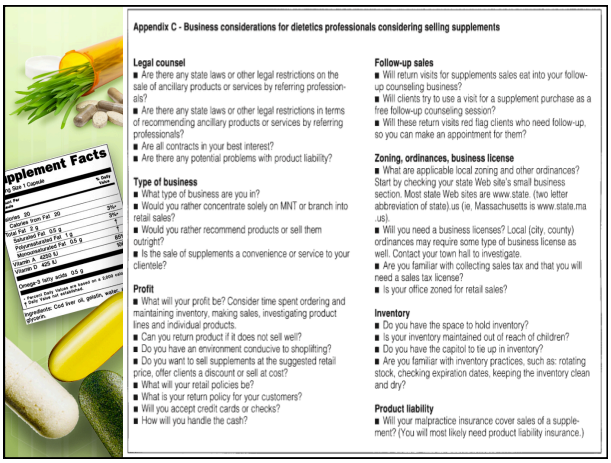
- Consumer Lab
- United States Pharmacopeia (USP)
- NSF International
- Non-GMO Project Verified


ConsumerLab.com
Celebrating 14 Years of Reporting 1999 – 2013
Be Sure It's CL Approved
Our Mission: To identify the best quality health and nutritional products through independent testing.
Home
Product Tests
-- Select a Review --
Warnings
Encyclopedia
News
Where to Buy
BECOME A MEMBER
Instant Access to Reviews for OVER 1,000 Products!
Quality Ratings and Product Comparisons
Expert Insights and More!
JOIN NOW
Warnings
Manufacturer of Joint, Weight Loss, Muscle Supplements and More Warned for Adulteration, Misbranding and Drug Claims
Maker of Liquid Omega-3 Supplements Warned For Manufacturing Violations
In the News
USA TODAY
USA Today's article "Vitamin D Doses Often Don't Match Labels, Study Says" mentions ConsumerLab.com's tests.
Recent ConsumerLab.com Reviews
Should You Take Calcium? Full Review
Photo: ConsumerLab.com
Wrong Amounts of Vitamin D and Pills That Don't Break Apart
New Report Reviews Calcium Supplements and Facts
Fish Oil, Krill Oil, Algal Oil and Calamari Oil Supplements Reviewed
Most Popular Reviews
Other Recent Reviews
Brands
Make Sure Your Multivitamin Passed! Check Results for 60 Products
Multivitamins Put to the Test; Defects Found in Over 30%.
Learn How to Choose a Probiotic That's Best for You; 29 Tested
Not All Probiotics Contain Listed Ingredients -- Find Out Which Deliver!
CoQ10 and Ubiquinol Supplements Reviewed
Quality Tests of 31 Products; Comparisons of Cost, Dose, and
Deficiencies Found in B-Complex Products; More Caffeine Than Expected in â€œEnergy Shotsâ€ Drinks
Tests of Energy Drinks, B-Complex and B Vitamin Supplements
Avoid Magnesium Supplements with Misleading Labels!
Best and Worst Quality Magnesium Supplements Identified.


Dietary Supplements- Bioethics and Sales


Bioethics & Dietary Supplementation
Autonomy: people have the right to control what happens to their bodies; access to health care freedom
Nonmaleficence: "first do no harm"
Beneficence: "do the most good"
Justice: be as fair as possible; be able to justify your actions
Misrepresentation: when boundaries of professional training and skill are exceeded; false and misleading advertisement or product promotion and endorsement
Duty to Refer: can protect patient from harm, can protect clinician liability; collaborate with others, seek counsel and/or make referrals as appropriate


Guidelines regarding the recommendation and sale of dietary supplements
CYNTHIA THOMSON, PhD, RD, FADA; CONNIE DIEKMAN, MEd, RD, FADA; ALLISON SARUBIN FRAGAKIS, MS, RD; CAROL MEERSCHAERT, RD; HAROLD HOLLER, RD; CATHY DEVLIN, RD
Note: Published in 2002, update under development by Academy Positions Committee
Dietary supplement sales have increased in the United States over the past decade. This trend has influenced the practice of dietetics in that dietetics professionals are increasingly called upon to provide recommendations to patients/clients regarding the use of specific supplements. Given our education and training in diet and nutrition, our profession is uniquely positioned to meet this need. However, for many dietetics professionals this is a new area of practice that requires continuing education, awareness of legal and regulatory issues, and an understanding of professional ethics. The sale of dietary supplements by dietetics professional presents a potential financial conflict of interest (both real and perceived) and could undermine the trust between patient/client and the dietetics professional. Therefore, the decision to sell dietary supplements should be cautiously evaluated.
In the Fall 2001, the House of Delegates of the American Dietetic Association requested the development of professional guidelines for dietetics professionals related to recommending and selling of dietary supplements in their practice. The Sale of Dietary Supplements Task Force was formed to respond to this charge.
This Task Force developed the following guidelines, which are meant to provide direction to dietetics professionals. Individual practitioners are advised to review the ADA/CDR Code of Ethics by the Profession of Dietetics (www.eatright.org/adacode.html) as well as consult experts in their area regarding the legal and regulatory issues specific to their location of practice. These guidelines should be considered as recommendations for best practice and are not enforceable except in regards to the ADA/CDR Code of Ethics. The Task Force has attempted to provide specific guidelines, which are relevant and practical for all dietetic professionals. In addition, the guidelines have been augmented with specific resources for both professional reference and continuing education as well as a business practice checklist for practitioners to ensure all pertinent issues have been addressed prior to expanding into this area of practice.
These guidelines and appendix were submitted to the House of Delegates for review. During the Spring HOD meeting, modifications were made to the guidelines based on member input. The following motion was adopted on May 5, 2002: "Therefore, be it resolved that the House of Delegates adopt the guidelines entitled, "Guidelines for Recommendations and
Cynthia Thomson, PhD, RD, FADA is an assistant professor, Nutritional Sciences, University of Arizona, Tucson, AZ, and a Member of Nutrition in Complementary Care, Research, and Nutrition Educator of Health Professionals Dietetic Practice Groups; Connie Diekman, MEd, RD, FADA Washington University in St. Louis, St. Louis, MO, Representing the House of Delegates (Professional Issues Delegate); Allison Sarubin Fragakis, MS, RD, Greenbrae, CA, author of ADA's The Health Professional's Guide to Popular Dietary Supplements, Member of Nutrition in Complementary Care and Sports, Cardiovascular and Wellness Nutritionists Dietetic Practice Groups; Carol Meerschaert, RD, Falmouth, ME, Member of Nutrition Entrepreneurs Dietetic Practice Group; Harold Holler, RD, director, HOD Governance, American Dietetic Association; Cathy Devlin, RD, manager, HOD Governance, American Dietetic Association
1158 / August 2002 Volume 102 Number 8



Appendix C - Business considerations for dietetics professionals considering selling supplements

Legal counsel
- Are there any state laws or other legal restrictions on the sale of ancillary products or services by referring professionals?
- Are there any state laws or other legal restrictions in terms of recommending ancillary products or services by referring professionals?
- Are all contracts in your best interest?
- Are there any potential problems with product liability?

Type of business
- What type of business are you in?
- Would you rather concentrate solely on MNT or branch into retail sales?
- Would you rather recommend products or sell them outright?
- Is the sale of supplements a convenience or service to your clientele?

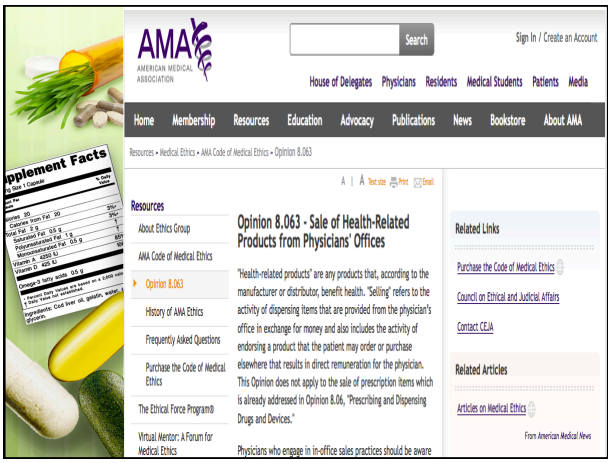
Profit
- What will your profit be? Consider time spent ordering and maintaining inventory, making sales, investigating product lines and individual products.
- Can you return product if it does not sell well?
- Do you have an environment conducive to shoplifting?
- Do you want to sell supplements at the suggested retail price, offer clients a discount or sell at cost?
- What will your retail policies be?
- What is your return policy for your customers?
- Will you accept credit cards or checks?
- How will you handle the cash?

Follow-up sales
- Will return visits for supplements sales eat into your follow-up counseling business?
- Will clients try to use a visit for a supplement purchase as a free follow-up counseling session?
- Will these return visits red flag clients who need follow-up, so you can make an appointment for them?

Zoning, ordinances, business license
- What are applicable local zoning and other ordinances? Start by checking your state Web site's small business section. Most state Web sites are www.state. (two letter abbreviation of state).us (ie. Massachusetts is www.state.ma .us).
- Will you need a business licenses? Local (city, county) ordinances may require some type of business license as well. Contact your town hall to investigate.
- Are you familiar with collecting sales tax and that you will need a sales tax license?
- Is your office zoned for retail sales?

Inventory
- Do you have the space to hold inventory?
- Is your inventory maintained out of reach of children?
- Do you have the capitol to tie up in inventory?
- Are you familiar with inventory practices, such as: rotating stock, checking expiration dates, keeping the inventory clean and dry?

Product liability
- Will your malpractice insurance cover sales of a supplement? (You will most likely need product liability insurance.)



Opinion 8.063 - Sale of Health-Related Products by Physicians

- Because of the risk of patient exploitation, physicians must take steps to **minimize financial conflicts of interest**
- Physicians must provide **financial disclosure** about arrangements with a manufacturer or supplier to sell health-related products (verbal *or* written)
- Disclosure includes informing patients of financial interests as well as about **availability of the product or equivalent products elsewhere**
- Provide **literature on risks, benefits, and limits of knowledge** regarding health-related product
- **Avoid exclusive distributorships** of health-related products which are available only through physicians' offices

Practice Pearl- have a written financial disclosure policy

ORIGINAL INVESTIGATION

Emerging Credentialing Practices, Malpractice Liability Policies, and Guidelines Governing Complementary and Alternative Medical Practices and Dietary Supplement Recommendations

A Descriptive Study of 19 Integrative Health Care Centers in the United States

Michael H. Cohen, JD; Andrea Hrbek; Roger B. Davis, ScD; Steven C. Schachter, MD; David M. Eisenberg, MD

19 Centers surveyed; inadequate DS policies at all

Background: Little is known about policies governing the integration of complementary and alternative medical (CAM) therapies and providers.

Methods: To document emerging approaches in 19 US hospitals regarding credentialing, malpractice liability, and pharmacy policies governing integration of CAM therapies and providers into conventional medical settings, we surveyed 21 academic medical centers and 13 non–academically affiliated hospitals that are nationally visible and are integrating CAM therapies into conventional medical settings. Of the 19 respondents, 11 were tertiary care hospitals, 6 were community hospitals, 1 was a freestanding center associated with a community-based hospital, and 1 was a university-based rehabilitation hospital.

Results: Institutions had no consistent approach to provider mix and authority within the integrative care team, and minimum requirements for professional liability insurance, informed consent disclosure, and hiring status. Less than a third had a formal (stated) policy concerning dietary supplements; those selling supplements in their pharmacy lacked consistent, evidence-based rationales regarding which products and brands to include or exclude. Although many hospitals confiscated patient supplements on admission, institutions had inconsistent criteria regarding allowance of home supply.

Conclusions: Hospitals are using heterogeneous approaches to address licensure, credentialing, scope of practice, malpractice liability, and dietary supplement use in developing models of integrative care. The environment creates significant impediments to the delivery of consistent clinical care and multisite evaluations of the safety, efficacy, and cost-effectiveness (or lack thereof) of CAM therapies (or integrative models) as applied to management of common medical conditions. Consensus policies need to be developed.

Arch Intern Med. 2005;165:289-295

PEDIATRICS®

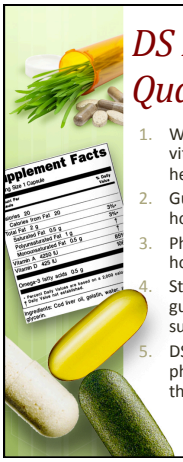
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

- **109 children's hospitals surveyed**
- **64% allowed staff to make recommendations about DS**
- **2% of hospitals had herbs on formulary, 99% had vitamins**
- **only 11% of hospitals satisfied 10 criteria necessary for perfect *DS Policy and Practices Quality Score***

Dietary Supplements: Inpatient Policies in US Children's Hospitals

Paula Gardiner, Russell S. Phillips, Kathi J. Kemper, Anna Legedza, Silas Henlon and Alan D. Woolf

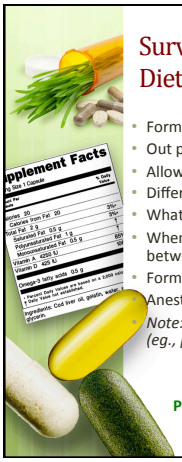
Pediatrics 2008;121;e775
DOI: 10.1542/peds.2007-1898



DS Policy and Practices Quality Score: 10 Criteria

1. Written policy on vitamins, minerals, herbs
2. Guidelines on use of home supply of DS
3. Physician order to use home supply of DS
4. Storage and dispensing guidelines for home supply
5. DS formulary created by pharmacy and therapeutics committee
6. DS formulary based on evidence of quality of DS
7. DS formulary based on evidence of safety of DS
8. DS formulary based on evidence of efficacy of DS
9. Required documentation in the patient record, including product name, common name, dosing, route, frequency, indication of use,
10. System to check/report drug-DS interactions

Gardiner et al. (2008). *Pediatrics*, 121(4), e775-781.

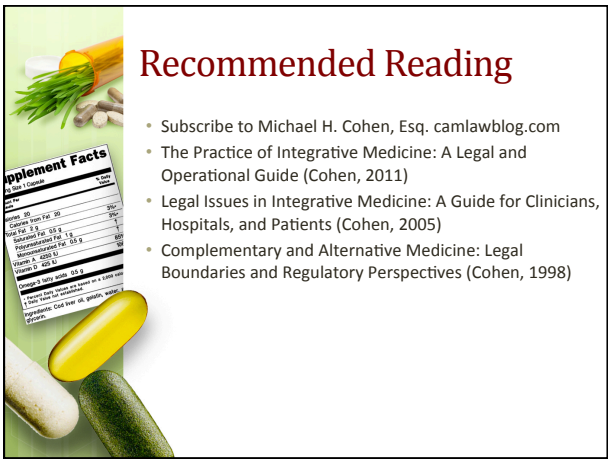


Survey of Integrative Health Care Centers Dietary Supplement Recommendations

- Formal stated dietary supplement policy?
- Out patient policy vs. inpatient policy?
- Allow staff to make recommendations about supplements?
- Difference in recommending vitamin/mineral vs. botanicals?
- What is institutional source of information for supplements?
- When making recommendations, does facility make distinctions between brands?
- Formulary inclusion and exclusion criteria?
- Anesthesia and surgery formal stated policy?
- *Note: also consider anticoagulant policy, vulnerable groups policy (eg., pregnancy, lactation, infants, children, adolescent, elderly)*

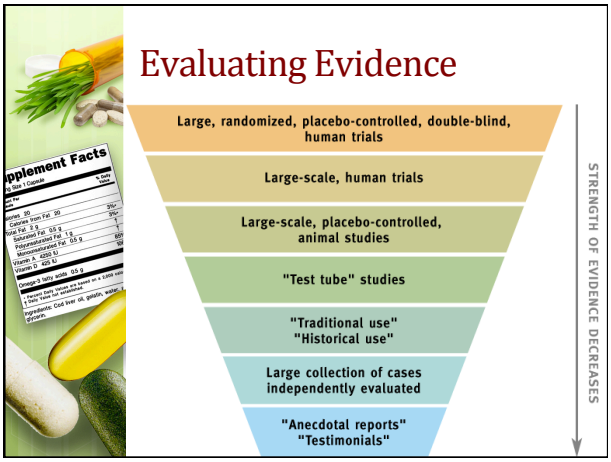
Practice Question: has your center established policies?

Source: Arch Intern Med. 2005; 165:289-295


Recommended Reading
Subscribe to Michael H. Cohen, Esq. camlawblog.com
The Practice of Integrative Medicine: A Legal and Operational Guide (Cohen, 2011)
Legal Issues in Integrative Medicine: A Guide for Clinicians, Hospitals, and Patients (Cohen, 2005)
Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives (Cohen, 1998)


The Science:
Evidence Based Medicine
Risk-Benefit Analysis &
Assumption of Risk


Evidence Based Medicine (EBM)
A systematic approach to gathering, evaluating, and using research findings, when available, to make a clinical decision


Evaluating Evidence
Large, randomized, placebo-controlled, double-blind, human trials
Large-scale, human trials
Large-scale, placebo-controlled, animal studies
"Test tube" studies
"Traditional use" "Historical use"
Large collection of cases independently evaluated
"Anecdotal reports" "Testimonials"
STRENGTH OF EVIDENCE DECREASES

Practice-Based Evidence and Patient Reported Outcomes

- Practice-based evidence promotes the value of knowledge and evidence gained from the practitioner's clinical experiences and observations
- Future research needed to develop metrics for patient reported outcomes for dietary supplement interventions
- Consider recording DS interventions and tracking DS outcomes in the Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII)

ANDHII
eat right. Academy of Nutrition and Dietetics Health Informatics Infrastructure

Risk Assessment Based on Strength of Evidence

Patient and clinician evaluate risks and benefits, discuss whether evidence is:

- Convincing
- Probable
- Possible
- Limited data to support or reject judgment

Practice Pearl: use this language in patient education

Assumption of Risk

- Recognizes the patient's responsibility for treatment choices
- **Assumes all treatments have potential risks** (and potential benefits)
- For patient: can serve **right to health care freedom**
- For clinician: can shield from malpractice liability

Practice Pearl: use this language in patient education- assumption of risk, right to health care freedom

Evidence vs. Harm Grading Strength of the Recommendation Taxonomy (SORT)

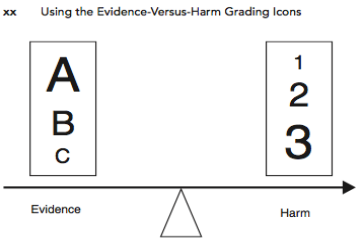
Grade A	Based on consistent, good-quality, patient-oriented evidence (e.g., systematic review or meta-analysis showing benefit, Cochrane Review with clear recommendation, high-quality patient-oriented randomized controlled trial). Example: Acupuncture for nausea and vomiting.
Grade B	Based on inconsistent or limited-quality patient-oriented evidence. Example: Ginger for osteoarthritis.
Grade C	Based on consensus, usual practice, opinion, disease-oriented evidence (e.g., study showing a reduction in blood sugar but no studies in humans to show a benefit to those with diabetes).

Grade 3 (most harm)	This therapy has the potential to result in death or permanent disability. Example: Major surgery under general anesthesia or carcinogenic effects of the botanical *Aristolochia* (birthwort).
Grade 2 (moderate harm)	This therapy has the potential to cause reversible side effects or interact in a negative way with other therapies. Example: Pharmaceutical or neutraceutical side effects.
Grade 1 (least harm)	This therapy poses little, if any, risk of harm. Examples: Eating more vegetables, increasing exercise, elimination diets, encouraging social connection.

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

Evidence vs. Harm Grading Icons

xx Using the Evidence-Versus-Harm Grading Icons

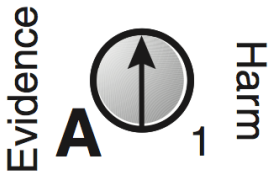


Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

Evidence A,1
Good quality evidence, little harm

Clinical Recommendation

- Exercise for diabetes management (A,1)

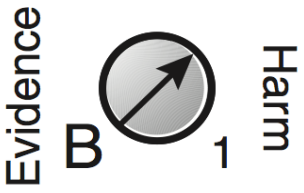


Practice Pearl: use this language in practice- good quality evidence, little harm

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

B,1
Limited quality evidence, little harm

- Hypnosis for irritable bowel syndrome (B,1)

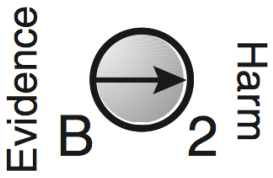


Practice Pearl: use this language in practice- limited quality evidence, little harm

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

B,2
Limited quality evidence, moderate harm

- Zinc supplementation for infectious diarrhea (B,2)

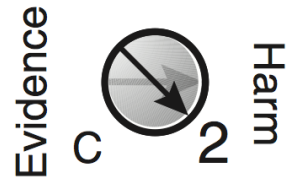


Practice Pearl: use this language in practice- limited quality evidence, moderate harm

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

C,2 Based on consensus, usual practice, disease oriented evidence, moderate harm

- Astragalus root for infectious hepatitis (C,2)

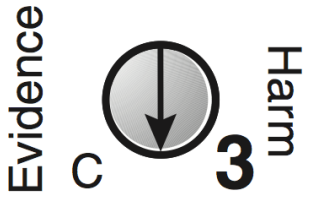


Practice Pearl: use this language in practice- based on consensus, usual practice, disease oriented evidence, moderate harm

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

C,3 Based on consensus, usual practice, disease oriented evidence, most harm

- *Aristolochia* (birthwort) to support immunity (C,3)



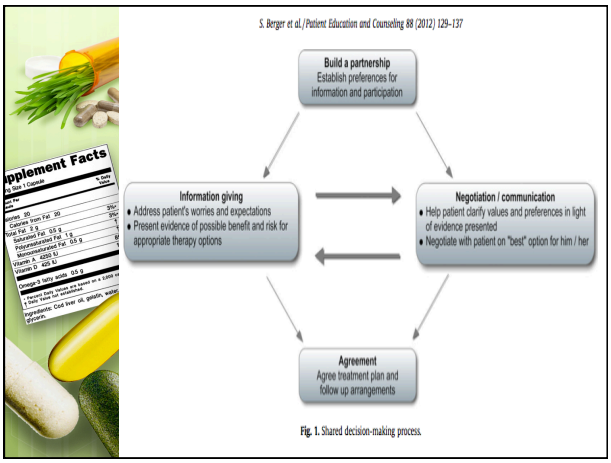
Practice Pearl: use this language in practice- based on consensus, usual practice, disease oriented evidence, most harm

Rakel, D. (2012). *Integrative Medicine, 3rd ed.*

The Art: Shared Decision Making

Shared Decision Making (SDM)

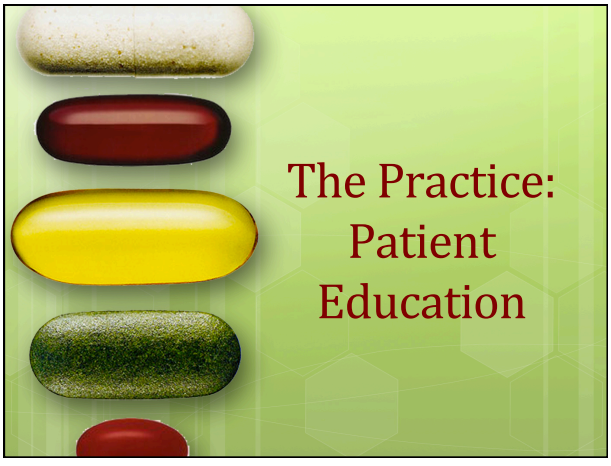
OUT	IN
• Medical paternalism	• Mutualism
• Informed consent and patient participation	• Informed shared medical decision making
• Patient centered care	• Person/client-centered care
• Compliance	• Adherence



Patient Limitations to SDM

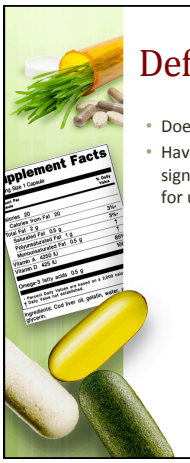
Limitations to evaluating information, such as

- Culture
- Language
- Literacy level
- Socioeconomic status
- Cognitive abilities



Risk Characterization Framework for Shared Decision-Making: Discuss with Client/Patient

- Assumption of risk
- Risk-benefit analysis
- Scientific names
- Use- structure/function vs. disease claim
- Where found/made
- Mechanism of action
- ***KNOWN*** safety
- ***KNOWN*** efficacy
- ***KNOWN*** side effects
- ***KNOWN*** drug interactions
- Medical contraindications
- At-risk populations
- **Drug/food/plant allergies**
- ***TYPICAL*** dose in studies
- Route of administration
- Lowest effective dose
- Dose response relationship
- **Dose escalation**
- Physiological levels versus upper limits and toxicity
- Start and **STOP** dates
- Brand quality/purity/identity
- **Sequential introduction**
- Subjective/objective monitoring
- **'Reasonably foreseeable' and adverse side effects**
- Adverse event reporting
- **Tapering, discontinuing and rotation**
- *Specific/focal* (short term) vs. *maintenance/preventive* (long term) regimens



Defining Safety

- Does not mean safe
- Having a **low incidence** of adverse reactions and significant side effects when adequate instructions for use are given

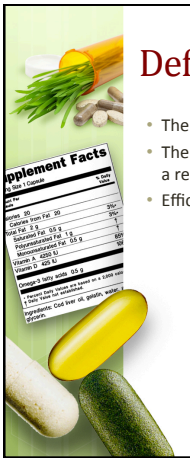
Evaluating & Discussing Safety

- Likely safe
- Possibly safe
- Possibly unsafe
- Likely unsafe
- Unsafe
- Limited data to support or reject a judgment

Practice Pearl: use this language in patient education

Evaluating & Discussing Safety

- Different doses affect safety
- Different uses, or **routes of administration**, affect safety
- **A product may be effective, but unsafe**
- No product is safe for ALL people ALL of the time
- Potential medical contraindications: kidney disease, liver disease, prescription medication users, immunocompromised
- Vulnerable groups: infants, children, adolescents, pregnant, lactating, elderly



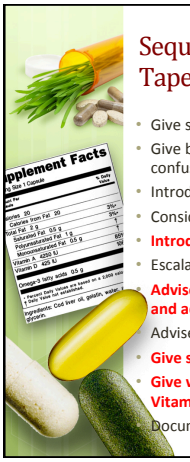
Defining Efficacy

- The **performance** of a drug or treatment
- The maximum ability of a drug or treatment to produce a result regardless of safety
- Efficacy differs depending upon use

Evaluating and Discussing Efficacy

- Likely effective
- Possibly effective
- Possibly ineffective
- Likely ineffective
- Ineffective
- Limited data to support or reject a judgment

Practice Pearl: use this language in patient education



Sequential Introduction, Dose Escalation, Tapering, and Discontinuing DS

- Give start dates or calendar (e.g., Days 1-3, Week 1, Week)
- Give brand name and **DS full name, not abbreviation** to avoid confusion with similar named DS (e.g., 7-keto-DHEA, DHEA, DHA)
- Introduce one supplement at a time (some exceptions)
- Consider starting with single ingredient vs. multi-ingredient
- **Introduce at lowest most effective typical dose in studies**
- Escalate dose as indicated and as tolerated
- **Advise on 'reasonably foreseeable side effects', adverse effects, and adverse event reporting**

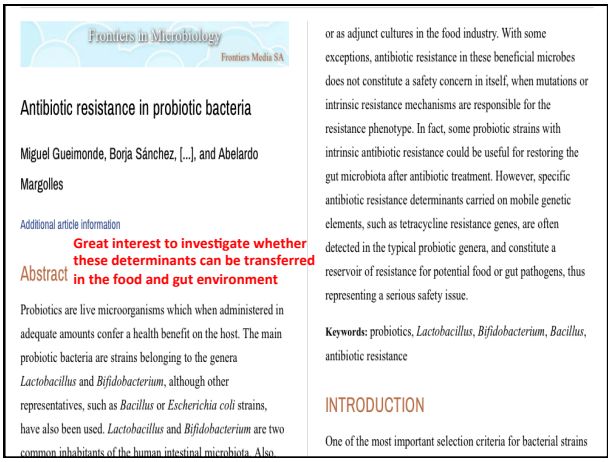
Advise on tapering as needed

- **Give stop/discontinue dates (e.g., x 30 days, x 3 months etc.)**
- **Give written instructions to patient, or 'Refer to WebMD Vitamin & Supplement Center for more information'**

Document 'written instructions provided'

Botanical Diversity in Dietary Supplementation

- Gives widest exposure to nutrients
- Minimizes repetition of naturally occurring toxins
- Decreases likelihood of exceeding upper limits for micronutrients and phytonutrients (ex. B vitamins and resveratrol)
- Minimizes likelihood of developing 'resistance' to herbs, probiotics etc.



Frontiers in Microbiology
Frontiers Media SA

Antibiotic resistance in probiotic bacteria

Miguel Gueimonde, Borja Sánchez, [...], and Abelardo Margolles

Additional article information

Great interest to investigate whether these determinants can be transferred in the food and gut environment

Abstract

Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host. The main probiotic bacteria are strains belonging to the genera *Lactobacillus* and *Bifidobacterium*, although other representatives, such as *Bacillus* or *Escherichia coli* strains, have also been used. *Lactobacillus* and *Bifidobacterium* are two common inhabitants of the human intestinal microbiota. Also

or as adjunct cultures in the food industry. With some exceptions, antibiotic resistance in these beneficial microbes does not constitute a safety concern in itself, when mutations or intrinsic resistance mechanisms are responsible for the resistance phenotype. In fact, some probiotic strains with intrinsic antibiotic resistance could be useful for restoring the gut microbiota after antibiotic treatment. However, specific antibiotic resistance determinants carried on mobile genetic elements, such as tetracycline resistance genes, are often detected in the typical probiotic genera, and constitute a reservoir of resistance for potential food or gut pathogens, thus representing a serious safety issue.

Keywords: probiotics, *Lactobacillus*, *Bifidobacterium*, *Bacillus*, antibiotic resistance

INTRODUCTION

One of the most important selection criteria for bacterial strains

Food Research International

Volume 57, March 2014, Pages 176–195

Review

Antibiotic resistance among commercially available probiotics

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Subjective and Objective Monitoring and Evaluation of Outcomes

- Pre and post intervention(s) plan
- Advise on, monitor and evaluate, and document **subjective** outcomes (fatigue, mood, bloating, gas etc.)
- Advise on, monitor and evaluate, and document **objective** outcomes (BP, weight, biochemical etc.)
- **DOCUMENT**
- **DOCUMENT**
- **DOCUMENT**
- **DOCUMENT DS interventions and track DS outcomes in the Academy of Nutrition and Dietetics Health Informatics Infrastructure (ANDHII)**

Don't Practice Medicine!

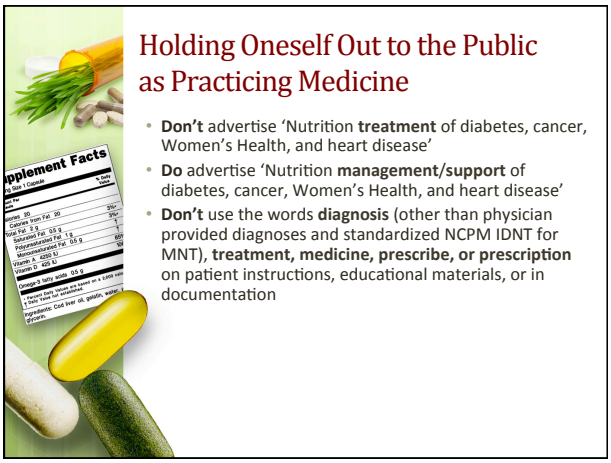
The practice of medicine is defined as:

- Diagnosing, preventing, treating, and curing disease
- Holding oneself out to the public as able to perform the above
- Using, administering, or prescribing drugs or 'medicinal preparations'

Source: Cohen M, A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing, 27 Ariz. State Law Journal 79, 1995.

Don't Diagnose, and Don't Treat

- **Don't use health claims or medical claims**
- Don't say, or document, glucomannan to treat hyperglycemia
- **Do use structure and function claims**
- Do say, and document, fenugreek to enhance, optimize, promote, aid, or maximize, carbohydrate metabolism; or 5-HTP to support sleep and mood; or glutamine to promote a healthy digestive tract



Holding Oneself Out to the Public as Practicing Medicine

- **Don't** advertise 'Nutrition **treatment** of diabetes, cancer, Women's Health, and heart disease'
- **Do** advertise 'Nutrition **management/support** of diabetes, cancer, Women's Health, and heart disease'
- **Don't** use the words **diagnosis** (other than physician provided diagnoses and standardized NCPM IDNT for MNT), **treatment, medicine, prescribe, or prescription** on patient instructions, educational materials, or in documentation

Dietary Supplements: Practice Policies

Dietary Supplement Policy/Informed Consent

- Assumption of risk
- Risk characterization framework for shared decision- making

Vulnerable groups policy

Drug nutrient interaction policy

Anesthesia and surgery policy

Anticoagulant policy

Adverse event reporting policy

Formulary policy with brand inclusion/exclusion criteria

Compounding pharmacy policy

Financial disclosure statement/policy

The End
Got a ?
Ask Me!

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