INSTRUCTIONAL DESIGN AND ASSESSMENT

An Elective Course on the Basic and Clinical Sciences Aspects of Vitamins and Minerals

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Objective. To develop and implement an elective course on vitamins and minerals and their usefulness as dietary supplements.

Design. A 2-credit-hour elective course designed to provide students with the most up-to-date basic and clinical science information on vitamins and minerals was developed and implemented in the doctor of pharmacy (PharmD) curriculum. In addition to classroom lectures, an active-learning component was incorporated in the course in the form of group discussion.

Assessment. Student learning was demonstrated by examination scores. Performance on pre- and post-course surveys administered in 2011 demonstrated a significant increase in students' knowledge of the basic and clinical science aspects of vitamins and minerals, with average scores increasing from 61% to 86%. At the end of the semester, students completed a standard course evaluation.

Conclusion. An elective course on vitamin and mineral supplements was well received by pharmacy students and helped them to acquire knowledge and competence in patient counseling regarding safe, appropriate, effective, and economical use of these products.

Keywords: vitamins, minerals, dietary supplements, pharmacy curriculum, elective course

INTRODUCTION

Use of dietary supplements is becoming increasingly popular among the general population in the United States as well as in other developed countries.¹ In the United States, more than half of the adult population takes dietary supplements on a regular basis.² Use of dietary supplements is more common among women, the elderly, Caucasians, socio-economically advantaged groups,³ and patients diagnosed with deadly diseases, such as cancer.⁴ Vitamins and mineral supplements are the major part of today's most popular dietary supplements.⁵ A few questionable and exaggerated claims that chronic conditions can be prevented or treated by dietary supplements have led to unprecedented growth in supplement use in the United States, with \$28 billion in sales annually.⁶ A substantial portion of this amount is spent on vitamins and minerals.

Although vitamins and minerals are perceived as beneficial and safe for human consumption, there are concerns

of potential adverse effects when consumed in excess.⁷ The prevalence of overconsumption of vitamins and minerals has been reported in the general population as well as in populations with altered health status.⁸ The use of certain vitamins and mineral supplements was associated with decreased occurrence of cancer in some specific populations of patients;⁹ however, other studies have reported no benefit¹⁰ or an increased risk of cancer and all-cause mortality as a result of taking these supplements.^{11,12} Furthermore, there is a risk of prescription drug and supplement interactions, specifically in the geriatric population who are concurrently taking multiple medications.¹³

The quality control of dietary supplements is voluntary and not strictly regulated by the Food and Drug Administration (FDA). According to a recent Government Accountability Office report,¹⁴ the FDA has minimal oversight and cannot force companies to provide documentation of scientific support for a claim in many cases. The United States Pharmacopeia (USP)¹⁵ offers a voluntary Dietary Supplement Verification Program for the manufacturers of dietary supplements. Similar verification processes and product standard tests for dietary supplements are performed by ConsumerLab.com, an independent company.¹⁶ Products earning USP or ConsumerLab.com certification have been manufactured

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under current good manufacturing practice, contain the listed ingredients in the indicated amounts that are bio-available, and are free from contaminants. Adherence to good manufacturing practice is more of a self-regulating choice. Consequently, it is not unusual to find substandard supplements being sold in the United States, possibly raising public safety concerns.

It is crucial that consumers have the most accurate information about the benefits and risks of taking dietary supplements. Pharmacists, as frontline healthcare professionals, can play a significant role in patient counseling on dietary supplements. Surveys conducted in Canada and Australia reported that pharmacy customers would prefer to consult pharmacists for advice on dietary supplements.¹⁷ Therefore, pharmacists must be equipped with evidence-based knowledge to provide an unbiased opinion and counseling about the safe use of dietary supplements. Several studies have found that pharmacists lack essential knowledge about vitamins, minerals, and other dietary supplements.¹⁸

While about 80% of US colleges and schools of pharmacy offer some kind of complementary and alternative medicines (CAM) course, most of these courses focus on herbal products rather than other forms of dietary supplements.¹⁹ This article will discuss the development and instructional design of an elective course focused on vitamins and minerals, and will describe assessment of student learning, students' perceptions of the course, and its implications for the practice of pharmacy.

DESIGN

Expected Outcomes

This 2-hour elective course, entitled Vitamins and Minerals, was developed and taught solely by the author. It was introduced into the PharmD curriculum in fall 2009 for second- and third-year pharmacy students at the Bradenton campus of Lake Erie College of Osteopathic Medicine (LECOM) School of Pharmacy. The primary goal of the course was to provide students with up-to-date and in-depth knowledge and comprehension of vitamins and minerals (Table 1) so that they could develop necessary competence in patient counseling to ensure safe, appropriate, effective, and economical use of vitamins and minerals. The students' learning objectives for this course were to understand: (1) the biochemical and physiological role of vitamins, minerals, and trace elements; (2) the pathophysiology of nutritional deficiencies of vitamins and minerals; (3) the potential benefits and therapeutic outcomes and risks of using vitamins and/or minerals as dietary supplements; and (4) nutrient-drug and nutrient-nutrient interactions. This research was granted exempt status by the Institutional Review Board of LECOM.

Table 1. Vitamins and Minerals Discussed in an Elective Course for Third-Year Pharmacy Students

Minerals and Trace Elements		
Aluminum	Iron	Selenium
Calcium	Magnesium	Sodium
Chromium	Manganese	Zinc
Copper	Potassium	
Vitamins		
Vitamin A (retinol)	Vitamin B9 (folic acid)	
Vitamin B1 (thiamine)	Vitamin B12 (cyanocobalamin)	
Vitamin B2 (riboflavin)	Vitamin C (ascorbic acid)	
Vitamin B3 (niacin)	Vitamin D (calciferol)	
Vitamin B5 (pantothenic acid)	Vitamin E (tocopherol)	
Vitamin B6 (pyridoxine)	Vitamin K (phyloquinone)	
Vitamin B7 (biotin)		

Course Implementation

In the fall semesters of 2009 and 2010, the numbers of students enrolled in the course were 39 and 41, respectively. However, because of continued student interest, the class size was increased to 50 students in fall 2011. The class met twice weekly for a total of 4 hours. Lectures were developed using online resources and published literature on basic and clinical science aspects of vitamins and minerals. The course content was divided into 2 modules (described below) and delivered using PowerPoint slide presentations. Students were given a recommended reading list of additional educational resources and a few books/book chapters.

In addition to the lectures, a 30-minute active-learning component was incorporated in each 2-hour session. Students were divided into small groups and instructed to discuss the material presented and then to formulate multiple-choice and true/false questions. This active-learning activity has been shown to enhance students' engagement with lecture materials and achievement of learning outcomes.²⁰ Each group shared their questions with the other students in the class by posting their questions on the discussion board in the school's Web portal or by e-mail. The instructor provided feedback to students on the content and quality of their questions, and whether the questions addressed key learning objectives.

Curricular Content

Lecture topics were divided into 2 modules as outlined in Table 2. In module 1, the students learned the biochemical and physiological functions of vitamins and minerals and their roles in pathophysiological states as a first step toward the development of skills necessary to

Table 2. Topics Covered in the Vitamins and Minerals Elective Course

Introduction
Current patterns and prevalence of use of vitamins and mineral supplements
Regulation of dietary supplements in the US
Module 1
The biochemical, physiological, and pathophysiological roles of minerals and trace elements:
Classifications and dietary sources
Roles in neuronal, muscle, and bone physiology
Maintenance of fluid volume and acid-base regulations
Pathophysiological aspects of high or low plasma levels
The biochemical, physiological, and pathophysiological roles of vitamins:
Classifications of vitamins, chemistry, dietary sources
Absorption and elimination
Roles in metabolism, growth and development
Roles in bone-mineral homeostasis
Modulation of immunity
Blood coagulation
Vitamin deficiency syndromes or disease
Module 2
Use of vitamins and minerals as dietary supplements:
Alleged therapeutic uses
Factors affecting biological functions/therapeutic effectiveness
Importance of quality and quality assurance programs
Evidence-based understanding of the efficacy of supplement use in chronic disease prevention
Discussion of available clinical trials of vitamins and minerals
Adverse effects of vitamins and minerals
Interactions with prescription medications and drug- and disease-interactions associated with vitamins and mineral supplements

gain evidence-based knowledge about a particular dietary supplement and its therapeutic outcomes.

Students learned about minerals that play significant roles in a number of physiological processes including in muscle and neuronal excitability (such as sodium, potassium, and calcium), acid-base regulations, maintenance of fluid volume, bone metabolism, synthesis, and functioning of proteins and enzymes. Students learned about different metalloenzymes and their roles in diabetes, heart disease, and brain function. Pathophysiological aspects of high or low plasma levels of certain minerals (clinical situations with hyponatremia, hypernatremia, hypokalemia, hyperkalemia, hypercalcemia, iron deficiency, etc) also were discussed.

Students were presented with materials on the classifications of vitamins, chemistry, dietary sources, dietary

requirement index (DRI), upper and lower limits of intake, and absorption and elimination processes. The biochemical and physiological functions of water soluble and fat soluble vitamins were discussed in detail (Table 2).

Module 1 concluded with a detailed discussion of vitamin deficiency syndromes and disease states. Students learned that although overt vitamin and mineral deficiency is rare in the United States, there is an unidentified prevalence of subclinical deficiencies. Most importantly, certain population groups are at risk of micronutrient deficiencies caused by pathophysiologic, physiologic, behavioral, and/or economic conditions. The signs and symptoms of syndromes or diseases and their pathophysiology related to deficiencies in thiamine, niacin, riboflavin, biotin, vitamin C, folic acid, and vitamin D were presented.

Learning the course content discussed in module 1 was intended to help students retrieve, analyze, and interpret scientific literature regarding a given dietary supplement, identify best possible evidence, and apply science-based knowledge to evidence-based patient care. Module 1 established the foundation for module 2, in which students learned about the rationale for use, potential benefits, therapeutic outcomes, and safety issues of vitamin and mineral supplements.

Module 2 began with a discussion of mineral supplements of calcium, magnesium, iron, potassium, zinc, chromium, and selenium. Students learned about different chemical forms and formulations of mineral supplements with varying proportions of elemental mineral contents. Individual vitamin and multivitamin supplements also were discussed.

The absorption and post-absorptive processes of different minerals and vitamins and the relevant factors affecting bioavailability were discussed. Students learned about different host factors such as the age, sex, physiologic state (eg, pregnancy), and host nutrient status affecting the bioavailability of vitamins and mineral. In addition, different formulation factors of oral dosage forms affecting bioavailability were discussed. Scientific evidence demonstrating that fillers, coatings, excipients, and surfactants of products affect the rate of release of a number of minerals and vitamins were presented to students.¹³

Additionally, in module 2, common quality control issues and quality assurance programs such as voluntary dietary supplement verification programs for the manufacturers of dietary supplements by the USP and ConsumerLab.com, an independent company, were discussed. The FDA has only minimal oversight and cannot force manufacturers to provide premarketing

documentation related to the quality and safety of their products. Consequently, dietary supplement manufacturers market products using false, exaggerated, and misleading claims. As an example, research findings were presented that showed where a number of vitamin and mineral supplements marketed in the United States and Canada failed to meet USP dissolution and disintegration standards.¹³ Similarly, students were also shown the inaccuracy of package label declarations identified and reported by US and UK trade associations. The inaccuracies identified included overages of 30% to 100% of declared value and underages of 15% to 57% for a number of vitamin products.¹³ This type of quality issue related to vitamins and mineral supplements in the marketplace can be minimized by promoting nutraceutical-grade products, which are or are close to USP pharmaceutical grade.

The results of well-known published clinical trials were discussed so that students could equip themselves with evidence-based knowledge on the use of dietary supplements (Table 3). Manufacturers' claims, at times, are based on the results of published epidemiological studies. However, epidemiological evidence is sometimes at great variance with evidence from randomized controlled trials. Subsequently, in this course, the risks of acute or chronic intake of excessive amounts of supplements, supplement-supplement interaction, and potential interactions with prescription medications were also presented.

Table 3. Major Clinical Trials Involving Vitamins and Minerals Discussed in the Vitamins and Minerals Elective Course

Clinical Trials	Vitamins/Minerals
Physician Health Study II (PHS II) ¹⁰	Vitamin E Vitamin C
Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study ¹¹	Alpha-tocopherol Beta-Carotene
Selenium and Vitamin E Cancer Prevention Trial (SELECT) ¹²	Selenium Vitamin E
Nurses' Health Study ³⁰	Selenium
Supplémentassions en Vitamines et Minéraux Antioxydants (SU.VI.MAX) ³¹	Vitamin C Alpha-tocopherol Beta-carotene Selenium Zinc
The Heart Outcomes Prevention Evaluation (HOPE) trial ³²	Vitamin E
Women's Health Study ³³	Vitamin E and/or Beta-carotene
Women's Health Initiative ³⁴	Calcium and vitamin D
Physician Health Study II (PHS II) ³⁵	Vitamin E Vitamin C

EVALUATION AND ASSESSMENT

Qualitative and quantitative data were collected from students enrolled in the course over 3 years (2009-2011) to measure learning outcomes. Students' knowledge of course content was evaluated by 3 standardized examinations. The first and second examination counted 25% and 30% of the course grade. The final examination was comprehensive and cumulative, and counted 35% of the course grade. All examinations included multiple-choice questions, true/false statements, and matching-format questions. Examination questions assessed student learning of course objectives.

The active-learning component, where students formulated questions, was 15% of the final grade. Student-generated questions were assessed based on content and quality, and whether they addressed key learning objectives. The group rather than the individual students was graded. Class average grades were 91 ± 4 in 2009, 90 ± 4 in 2010, and 90 ± 5 in 2011, demonstrating students' mastery of course content and knowledge gained.

In addition to the traditional examinations, in 2011, pre- and post-course assessments were used to evaluate students' baseline knowledge and understanding of basic and clinical science concepts of vitamins and minerals. A 30-item multiple-choice test was administered to students on the first and last day of the Vitamins and Minerals elective course in fall 2011. Students were not informed in advance about the pre- and post-course tests. The questions assessed students' knowledge of the chemistry, biochemical and physiological functions, and pathophysiological aspects of vitamins and minerals.

The pre-course assessment results showed that students had a basic knowledge of chemistry, such as the chemical names of vitamins and some deficiency syndromes. However, students scored low on questions dealing with biochemical and physiological functions, as well as the clinical aspects of vitamins and minerals. The class average on the precourse test was 61%; the class average on the postcourse test was significantly higher (86%, $p < 0.001$). During the last week of the course, students were asked to provide feedback on the rationale, goals, and objectives of the course; teaching strategies; and overall implementation of the course using an online survey instrument (Table 4). The respondents indicated their degree of agreement or disagreement with individual statements using a 7-point Likert scale (range: 1 = strongly disagree to 7 = strongly agree). One-way ANOVA followed by Tukey posttest was performed to determine any differences among responses of classes of 2009-2011.

Students highly rated the development, teaching strategies, and implementation of the course. On the question

Table 4. Final Course Evaluation for the Vitamins and Minerals Elective Course (2009-2011)

Survey Items	Median Response (2009), n=17	Median Response (2010), n=39	Median Response (2011), n= 47
I understand the purpose of this course	6.6	6.6	6.7
I am clear on how I will use this course as a pharmacist	6.6	6.6	6.8
The course goals and objectives were made available in a timely manner	6.4	6.6	6.6
The way the course was organized helped me learn the material	6.4	6.7	6.4
The course goals and objectives were clear, concise, comprehensive, and understandable	6.5	6.6	6.1 ^a
The course materials (eg, PowerPoint slides, text, notes) were valuable	6.5	6.7	6.3
The course evaluation measures (eg, exams) were consistent with the goals and objectives of the course	6.5	6.7	6.2
The amount of curriculum time devoted to this course was adequate	6.4	6.5	6.2
The materials were accessible and made available in a timely manner	6.1	6.9 ^b	6.6 ^c

^a $p < 0.05$ (2010 versus 2011)

^b $p < 0.01$ (2009 versus 2010)

^c $p < 0.05$ (2009 versus 2011)

“I am clear on how I will use the information presented in this course as a pharmacist,” the response was overwhelmingly positive (98% of the students agreed or strongly agreed). Ninety-five percent of the students agreed or strongly agreed that the course objectives and goals were clear, comprehensive, and understandable. However, the degree to which students agreed with this question differed significantly between the classes of 2010 and 2011 (median response 6.6 and 6.1 respectively, $p < 0.05$). More than 90% of students also agreed/strongly agreed that the course assessment measures were consistent with the goals and objectives of the course.

The course evaluation also asked students to comment regarding the development, teaching strategies, implementation, and other aspects of the course. Students' comments were overwhelmingly positive. Students most frequently commented that this course should be a part of the required curriculum as it helped them acquire knowledge and competence in patient counseling that would ensure safe, appropriate, effective, and economical use of vitamins and minerals as dietary supplements. The incorporation of the in-class active-learning activity was well-received by students. Students indicated that the group discussion and writing questions reinforced their learning experience.

DISCUSSION

As one of the most trusted health care professionals with unique availability and accessibility to patients, pharmacists are in the forefront in guiding patients regarding the use, efficacy, and safety of dietary supplements. Studies show that pharmacists are frequently asked about dietary supplements and natural products.¹⁸

However, pharmacists lack vital knowledge related to dietary supplements and are not confident in patient counseling. Similarly, pharmacy students perceive their knowledge about the appropriate use of supplements as inadequate.²¹

During the last decade, awareness about the need for inclusion and integration of evidence-based training on dietary supplements in the health profession curricula has increased. Several national pharmacy professional organizations have acknowledged the need for training pharmacists about dietary supplements.^{24,25} The American Association of Colleges of Pharmacy has identified the need for curricular change to incorporate CAM courses in pharmacy curriculum.²⁵ In 2005, a competency statement addressing whether pharmacists can provide sufficient information on the documented uses and safety profiles of dietary supplements was added to the North American Pharmacist Licensure Examination.²⁶ Similarly, the Accreditation Council for Pharmacy Education Standards for Accreditation Guidelines, version 2, provided advice on incorporating classroom/lecture-based coursework on dietary supplements and evaluation of their efficacy, safety, and possible interactions with prescription drugs.²⁷

In the United States, many pharmacy colleges and schools are incorporating CAM courses in the curricula that address mainly natural or herbal products.¹⁹ Bonafede and colleagues²⁸ developed a 3-credit elective course on dietary supplements for third-year PharmD students comprised of discussions on dietary supplements based on a widespread therapeutic categories such as disease prevention, immune health, men's and women's health, weight loss, cardiovascular diseases, neuropsychiatric conditions,

bone and joint health, and athletic performance. Atayee and colleagues²⁷ designed and implemented a small-group self-guided active-learning CAM course and assessed changes in first-year PharmD students' attitudes and knowledge of CAM.

Although vitamins and minerals constitute the majority of dietary supplements consumed by Americans, it is unclear from published studies how and to what extent topics on vitamins and minerals are covered in US pharmacy school curricula. This paper is the first to describe an integrated approach to teaching the basic and clinical sciences pertaining to the use of vitamin and mineral supplements for human health and treatment of disease.

The major strength of the course is that it provided students with a strong background on the biochemical and physiological functions of vitamins and minerals in the body and their roles in disease states (module 1). Then the course progressed to clinical information (module 2) so that students would be able to integrate their knowledge with a thorough understanding of potential outcomes of using vitamins and minerals as dietary supplements. For example, in module 1, chemical and biochemical functions of selenium were discussed. In animal models, selenium appears to function as an antioxidant and its deficiency was found to be associated with an increased incidence of cancer. In module 2, students learned that the incidence of cancer or cancer deaths was found to be lower in patients with high blood levels of selenium or taking selenium supplements according to several human observational studies and randomized control trials. However, in the Nurses' Health Study in 1982,³⁰ over 60,000 participants observed for 3.5 years showed no reduction in the risk of cancer. Finally, students were introduced to 2 long-term studies, the SU.VI.MAX study³¹ in France and the Selenium and Vitamin E Cancer Prevention Trial (SELECT, 35,000 participants, seven years),¹² in the United States and Canada. Both of these studies found the use of the supplements to be associated with an increased incidence of prostate cancer compared to a placebo group. Apart from the studies of selenium and cancer, students also learned that current evidence is insufficient to recommend selenium for the prevention of coronary artery disease, HIV, and arthritis. Another example is the discussion of physiological and pathophysiological roles of calcium, clinical manifestations of hypo- and hyper-calcemia, different calcium supplements and their formulations, uses, and finally the recent clinical studies relating calcium supplements and risk of cardiovascular events. Students also learned that randomized large-scale trials in the last two decades have shown that vitamin supplements are not only ineffective

for the majority of population, but may be deleterious to health. Similarly, several other well-known clinical trials^{10,11,32-35} involving vitamins and minerals were discussed so that students learn evidence-based decision making on the use of a selected vitamin and mineral dietary supplement. Thus, the strengths of this course include the in-depth instruction on the basic science related to vitamins and minerals and then integration of that knowledge into clinical practice. This course is offered at a time when students make the transition from classroom-based courses to providing pharmaceutical care to patients in experiential courses. The course provides educational goals to increase the knowledge of next generation pharmacists, which will in turn benefit the profession of pharmacy and consumer health.

While the course outcomes were satisfactory in terms of students' learning and acquiring knowledge, its effectiveness and applicability in direct patient care is not known. Additional research is needed to measure the lasting impact of this course in the practice setting. It would be interesting to gather data from students who took this course and are now practicing pharmacists. The goal of future research would be to capture translational data from this elective course to clinical practice.

SUMMARY

A comprehensive elective course on vitamins and minerals was developed and implemented into the PharmD curriculum. Based on learning assessments and students' course evaluations, the expected outcomes for the course were met and the course helped students to acquire knowledge and competence in patient counseling to ensure safe, appropriate, effective, and economical use of vitamins and minerals as dietary supplements. Other colleges and schools of pharmacy may consider the development of a similar course focusing on the basic and clinical science aspects of vitamins and minerals.

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