Ethics in Public Health Research

Multivitamin–Mineral Supplements in the Older Americans Act Nutrition Program: Not a One-Size-Fits-All Quick Fix

Melissa Ventura Marra, PhD, RD, and Nancy S. Wellman, PhD, RD, FADA

We challenge the suggestion of Congress that the Older Americans Act (OAA) Nutrition Program should provide multivitamin–mineral supplements (MVMs) in addition to meals. MVMs are not a quick fix for poor diets. They do not contain calories, protein, essential fatty acids, or fiber, nor do they adequately address nutritional gaps of some vitamins and minerals.

Older adults with chronic health conditions who take multiple medications are at greater risk than the general healthy population for nutrient–drug interactions and toxicity. The OAA Nutrition Program is not an appropriate venue to indiscriminately distribute MVMs, because there is insufficient evidence of their benefits and safety.

The program's limited funds and efforts should instead be directed to nutrient-dense healthy meals, quality food service, and greater accessibility to individualized nutrition services. (*Am J Public Health.* 2008;98:1171–1176. doi: 10.2105/AJPH.2007.122762)

THE OLDER AMERICANS ACT

(OAA) Nutrition Program provides nutritious congregate (sometimes called senior dining) and home-delivered (commonly called meals on wheels) meals and nutrition services to older adults who are at higher nutritional risk than the older population in general.[1–3] Program participants are older, have lower incomes, and may have more limited access to food than the older adult population as a whole. In addition, adults receiving home-delivered meals are frailer and have a greater number of functional impairments caused by nutrition-related diseases and conditions.[1]

As part of the 2006 reauthorization of the OAA, Congress, for the first time, provided an opinion in "sense of Congress" language (i.e., a formally expressed opinion about a subject of current national interest) regarding nutrition's contribution to the health of older adults.[4] Congress stated that although diet is the preferred source of nutrition, use of a single daily multivitamin–mineral supplement (MVM) may be an effective, safe, and inexpensive way of addressing nutritional gaps that exist among older adults, especially the poor, to help prevent common nutritional deficiencies.[4]

According to Congress, nutrition providers should consider whether

> individuals participating in congregate and home-delivered meal programs would benefit from a single, daily multivitamin-mineral supplement that is in compliance with all applicable government quality standards and provides at least 2/3 of the essential vitamins and minerals at 100% of the daily value levels as determined by the Commissioner of Food and Drugs.[4]

We assess the potential benefits and risks of the indiscriminate addition of MVMs to meals in the OAA Nutrition Program.

OLDER AMERICANS ACT NUTRITION PROGRAM

Each year the OAA Nutrition Program serves about 238 million meals to 2.6 million older adults, approximately 59% of whom are homebound. With an annual total expenditure of $1.23 billion, including a $735 million federal appropriation, the OAA Nutrition Program is the nation's largest food and nutrition assistance program targeting older adults.[5]

The purpose of the OAA Nutrition Program is to reduce hunger and food insecurity, promote socialization, and promote the health and well-being of older adults.[6] To this end, the OAA requires that meals supply at least one third of dietary reference intakes (DRIs) and comply with the current Dietary Guidelines for Americans (DGAs) per OAA section 339. State units on aging, and American Indian tribal organizations are responsible for implementing the federal guidelines. In addition to meals, the OAA Nutrition Program provides services such as nutrition screening, assessment, education, and counseling.[1]

The OAA allots federal funds for meals, not MVMs. It does not allow the content of MVMs to count toward meeting the nutrient requirements for meals. If alternate funding sources (state or local) were used to purchase MVMs, meals themselves would still be required by federal law to supply one third of DRIs (i.e., recommended dietary allowances or adequate intakes) and be in agreement with the DGAs.

The midday meal provided to program participants is often their primary source of food for the day. It provides at least 50% of the day's total food intake for

66% of home-delivered meal participants and 56% of congregate meal participants.[1] The meal provides one to two thirds of participants with their only daily source of foods from important groups such as fruits, vegetables, dairy products, meats, and grains. The program also provides active social engagement for congregate participants. For homebound participants, it serves as a social link to the community and helps delay institutionalization.[1] Demand exceeds current funding, as evidenced by waiting lists in at least 41% of home-delivered meal programs.[3]

The cost of providing MVMs would decrease the amount of money available for healthful meals. At a generally estimated cost of $0.10 per pill,[7] providing an MVM with each of the 238 million meals served annually[5] calculates to a cost of almost $24 million. Without additional funds, providing MVMs would decrease the total number of meals served by about 4.8 million each year; as a result, either fewer people would receive meals or fewer meals would be provided per person. It might also increase waiting lists for those most in need of meals.

Dietary Reference Intakes

The most recent versions of the DRIs and DGAs are the foundation for federal nutrition policy and guide the planning of OAA Nutrition Program meals. DRIs are a set of nutrient-based reference values established by the Food and Nutrition Board of the Institute of Medicine that include recommended dietary allowances, adequate intakes, estimated average requirements, and tolerable upper intake levels. Recommended intakes for individuals are expressed as recommended dietary allowances (or adequate intakes when less information is available).[8] Tolerable upper intake levels are the maximum daily intake levels unlikely to result in adverse health effects.[8]

Gender-specific recommended dietary allowances and adequate intakes include categories for individuals aged 51 through 70 years and for those older than 70 years. In comparison with younger adults, nutrient recommendations for adults older than 50 years are higher for calcium, vitamin B_6, and vitamin D and lower for iron (among women) and chromium.[9–11] Vitamin D recommendations are higher still for adults older than 70 years. The Institute of Medicine suggests that older adults obtain most of their vitamin B_{12} from fortified foods or supplements, because up to 30% of these individuals are unable to absorb B_{12} from conventional foods.[10]

An individual's requirement for a particular nutrient may be higher or lower than the recommended dietary allowance or adequate intake because of his or her genetic makeup, disease status, or medication use. Declines in kidney function, a common condition in older adults, can reduce excretion of some micronutrients, such as potassium, thereby decreasing the dietary requirement and increasing the potential for excess intake.[12] Some medications (e.g., anticonvulsants, thyroid hormones, antibiotics, anti-ulcer drugs, and diuretics) alter the body's absorption, excretion, or use of nutrients, thereby increasing requirements and risk of inadequacy.[13]

Intakes at levels higher than recommended dietary allowances and adequate intakes may be needed to correct deficiency states or to meet requirements that are increased as a result of diseases or medications. In a study of 50 community-dwelling older adults, 35% were found to be zinc deficient.[14] Among these individuals with zinc deficiencies, those whose diets were supplemented with 45 g of zinc per day (409%–563% of the recommended dietary allowance) for a year not only had higher plasma zinc levels but, more important, exhibited greater decreases in markers of oxidative stress and a lower incidence of infection than those receiving a placebo.

Dietary Guidelines for Americans

The US Department of Health and Human Services and the US Department of Agriculture translate nutrient-based recommendations (recommended dietary allowances and adequate intakes) into food-based recommendations via the DGAs. The US Department of Agriculture Food Guide suggests that a person requiring 1600 calories or 2000 calories per day, respectively, would need to eat about 5 or 5.5 oz-equivalents of lean meat or beans, 3 cups of milk, 5 or 6 oz-equivalents of grains (50% as whole grain), 1.5 or 2 cups of fruit, 2 or 2.5 cups of vegetables, and 22 or 27 g (5 or 6 tsp) of oil each day to meet recommended micronutrient intakes.[15] Specific energy and food group recommendations vary according to a person's age, gender, height, weight, and physical activity level.

The 2005 position of the DGAs on the use of dietary supplements is as follows:

> A basic premise . . . is that nutrient needs should be met primarily through consuming foods. Foods provide an array of nutrients (as well as phytochemicals, antioxidants, etc.) and other compounds that may have beneficial effects on health. In some cases, fortified foods may be useful sources of one or more nutrients that otherwise might be consumed in less than recommended amounts. Supplements may be useful when they fill a specific identified nutrient gap that cannot or is not otherwise being met by the individual's intake of food. Nutrient supplements cannot replace a healthful diet. Individuals who are already consuming the recommended amount of a nutrient in food will not achieve any additional health benefit if they also take the nutrient as a supplement. In fact, in some cases, supplements and fortified foods may cause intakes to exceed the safe levels of nutrients.[15(p30)]

According to the DGAs, people older than 50 years should meet their recommended dietary allowance for vitamin B_{12} by either eating foods fortified with vitamin B_{12} or taking a dietary supplement. In addition, it is noted in the DGAs that older adults, especially those who are homebound and have little or no exposure to sunlight, are at risk for low serum vitamin 25-hydroxyvitamin D concentrations. Low serum levels are associated with increased risk of

bone loss, fractures, and falls and decreased muscle strength. Older adults may need 1000 IU per day (167% of adequate intake) to reach and maintain adequate serum vitamin D levels.[15]

MULTIVITAMIN–MINERAL SUPPLEMENTS

Many community-residing older adults, particularly those with low incomes[16] and those who are homebound,[17] are unable or unwilling to eat enough food or the right types of foods to meet recommended intakes of vitamins A, B_6, C, D, E, and K, as well as calcium, magnesium, potassium, zinc, and fiber.[18] A study of 348 homebound older adults participating in a meal-delivery program showed that 27% had inadequate intakes of 6 or more nutrients.[17] A combination of fortified foods, liquid nutrition supplements, and supplement forms of nutrients may be necessary to fill the gaps between recommended and actual intakes.

Effectiveness in Filling Nutrient Gaps

The extent to which an MVM can be effective in filling nutrient gaps depends, in part, on the types and amounts of nutrients a supplement provides. Because there is no standard regulatory definition, MVMs differ substantially with respect to content (i.e., types, numbers, and amounts of vitamins, minerals, nonnutrient ingredients, and excipients).

Most single daily MVMs contain amounts close to 100% of the daily value for zinc and vitamins A, B_6, C, and E and thus may fill these gaps.[19] However, even MVMs formulated specifically for older adults may not supply substantial quantities of vitamins D and K, calcium, magnesium, potassium, and fiber, and therefore they may not adequately fill nutrient gaps. In the case of some nutrients, low amounts in MVMs are an issue of practicability as opposed to manufacturer choice. For example, the bulky nature of calcium compounds makes it impossible for one-pill-a-day MVMs to contain 100% of the daily value in a reasonably sized pill. And for some nutrients such as magnesium, it is a matter of safety. For instance, providing 100% of the daily value for magnesium (400 mg) as established by the Food and Drug Administration for use in nutrition labeling in supplement form would exceed the tolerable supplemental magnesium upper intake level of 350 mg/day.

Even if an MVM provides nutrients at levels equal to 100% of the daily value, it may not provide 100% of recommended dietary allowances or adequate intakes for older adults because daily value percentages for most micronutrients are calculated on outdated (1968) recommended dietary allowances. For example, an MVM that contains 100% of the daily value for vitamin D provides only 67% of today's recommended dietary allowance or adequate intake for adults older than 70 years. Supplement labels have not been updated to reflect current nutrient recommendations and are not specific for older adults. MVMs should be selected on the basis of types and actual amounts of nutrients rather than percentage of daily values.

According to the "sense of Congress" recommendation, MVMs should provide 100% of the daily value for at least two thirds of essential vitamins and minerals.[4] An unanticipated consequence of this language may be the selection of an MVM that does not supply the subset of nutrients with the most public health significance.

Effectiveness in Preventing Nutrient Deficiencies

The next issue is whether "filling nutrient gaps" with supplements results in health benefits. The benefit of consuming the recommended amount of a nutrient depends on the criteria used to define adequacy. For some nutrients, recommended intakes are the amounts needed to prevent deficiency disease; for others, these intakes are the amounts needed to reduce risk of chronic disease. In the case of nutrients with adequate intakes, recommended levels are often based on estimates of the mean intakes of healthy groups.

Recommended intakes may be higher than amounts needed to prevent deficiency disease. For this reason and because of individual variations in requirements, intakes below recommended levels should not be construed as nutrient deficiencies. For example, the recommended dietary allowance for vitamin E is based on the amount needed to prevent hydrogen peroxide–induced hemolysis, a functional end point of deficiency.[20] National data show that 96% of US adults have inadequate intakes, yet clinical symptoms of deficiency are rare in healthy individuals. Dietary assessment data must be combined with clinical, biochemical, and anthropometric data to evaluate nutritional status and diagnose deficiency states.

Overt micronutrient deficiency diseases (e.g., scurvy, beriberi) are no longer common in the United States. Low or inadequate vitamin and mineral intakes may, however, place older adults at risk of subclinical or marginal deficiencies. More data are needed on associations of nutrient intakes from MVMs with blood concentrations and how they relate to functional and clinical measures of nutrient adequacy and status. Research in this area is complicated because the biological markers and cut points needed to assess nutritional status and identify subclinical deficiencies are lacking for several nutrients.[21]

Efficacy also depends on nutrient bioavailability. Factors affecting bioavailability include an individual's nutrient status, the chemical form of the nutrient, the presence of competing chemicals in the intestine, the concentration of food components that bind to the nutrient and make it unavailable for absorption (i.e., phytates), intestinal transit time, and nutrient–nutrient interactions. Nutrient bioavailability and individual requirements can confound research results.

Few studies involving randomized controlled designs have investigated the effects of MVMs on micronutrient status. In one study, individuals taking MVMs for 8 weeks exhibited greater

improvements in plasma status of vitamins B_6, B_{12}, C, D, and E than individuals using a placebo, but they did not show greater improvements in vitamin A, thiamin, or measures of antioxidant defenses and cytokine production.[22] Investigations of the effectiveness of MVMs in preventing infections have produced conflicting results.[23] Evidence suggests that combined use of calcium and vitamin D supplements reduces bone loss and fractures in postmenopausal women.[24,25] Single daily MVMs, however, do not provide recommended amounts of calcium and vitamin D for older adults.

A National Institutes of Health panel concluded that evidence is insufficient to determine whether regular use of an MVM can play a part in the primary prevention of chronic disease among healthy adults.[24] A meta-analysis of antioxidant supplements (often high amounts) assessed in low- and high-bias risk trials focusing on primary and secondary disease prevention showed no significant effect on mortality. However, when only low-bias risk trials were considered, beta-carotene, vitamin A, and vitamin E were found to increase mortality.[26]

Safety and Quality

Another conclusion of the National Institutes of Health panel was that "the current level of public assurance of the safety and quality of MVMs is inadequate."[24(p370)] The panel found possible safety concerns for some nutrients in MVMs.[24] The potential for adverse effects is greater among older adults because they have more health conditions and use more medications than does the general population. Adverse events can stem from nutrient–drug interactions, excess nutrient intakes, and use with certain health conditions and surgical procedures. In addition to the total intake of a nutrient, risk of harm from MVMs depends on the susceptibility of the individual.[27] The OAA Nutrition Program serves a vulnerable population.

Vitamins and minerals in MVMs may interact with certain drugs and result in adverse clinical outcomes caused by an increase or decrease in nutrient or drug concentrations or the synergistic effect of combined compounds. For example, both iron[28] and calcium[29] supplements can interfere with the absorption of thyroid hormone medications, decreasing their effectiveness. Taking an MVM containing vitamin K on an inconsistent basis could decrease the effectiveness of anticoagulant medications.[30]

The specific needs of older adults must be considered when selecting types and forms of nutrients in supplements. Older adults are generally at greater risk for health problems associated with excess as opposed to deficient iron stores.[31] They should not take an MVM containing iron unless they are iron deficient. In addition, consumption of too much preformed vitamin A or retinol (i.e., more than 214% of the recommended dietary allowance or 100% of the daily value, an amount sometimes found in MVMs), but not beta-carotene, has been associated with increased hip fracture risk among postmenopausal women.[32] MVMs that provide a portion of the vitamin A from beta-carotene may be a better choice for older adults if they do not smoke.

Another safety concern is the potential for excess nutrient intakes from combinations of dietary supplements and fortified foods. Some fortified foods such as breakfast cereals contain nutrients at levels comparable to MVMs. Older adults who eat a fortified breakfast cereal and take an MVM are at increased risk of excess folic acid intake.[33]

Many older adults are unaware that too much of a nutrient can be detrimental to one's health. One study showed that 63% of MVMs users also supplemented with at least one other single nutrient.[34] Those who take an MVM supplement in addition to consuming a diet rich in fortified foods (e.g., cereals, juices), liquid meal replacements (e.g., Ensure, Sustacal), or single-nutrient supplements may be consuming nutrients in amounts that exceed tolerable upper intake levels. The nutrients most likely to exceed these levels are iron, zinc, vitamin A, niacin, and folate.[19] The risk of adverse health effects increases as intakes exceed the tolerable upper intake level.[8] Excessive levels of folic acid may mask or precipitate vitamin B_{12} deficiency, which, if left untreated, can lead to progression of neurological complications.[10] Effects of preformed vitamin A toxicity include liver abnormalities and reduced bone mineral density.[11]

Adverse events associated with MVMs have been reported to the American Association of Poison Control Centers and the US Food and Drug Administration (FDA) MedWatch system with some frequency.[24] The national 2002 Health and Diet Survey showed that 13% of adult users of MVMs reported adverse events, including abdominal pain, blood pressure problems, nausea, vomiting, allergy, dizziness, itching, and rash.[35]

Unlike regulations for drugs, regulations for dietary supplements do not require manufacturers to evaluate and prove safety (or efficacy) prior to marketing. As is the case with all dietary supplements, MVMs are regulated as a category of food by the FDA Center for Food Safety and Applied Nutrition under the Dietary Supplement Health and Education Act[36] of 1994.

Most MVMs contain ingredients sold before the Dietary Supplement Health and Education Act was enacted and therefore, legally, are presumed to be safe on the basis of their history of use. The FDA can remove existing ingredients from the market if the product is proven to be unsafe.[36] The FDA MedWatch program tracks consumer safety reports on supplements, but manufacturers were not required to report adverse effects until the Dietary Supplement and Nonprescription Drug Consumer Protection Act[37] was passed. This law requires that, as of December 2007, serious adverse events be reported and all adverse event records (whether serious or not) be maintained for 6 years and made available for FDA review.

Another concern is supplement quality. Congress recommended that MVMs be in compliance with all applicable government quality standards. Despite any such government standards, reports of poor-quality supplements, including MVMs, are often reported by the media. According to a for-profit organization that independently tests products, 11 of 21 MVMs failed with respect to at least 1 of the following quality indicators: providing ingredients as listed on the label, dissolving properly, and being free from contaminants such as heavy metals.[38]

To help address quality issues, the FDA issued a final rule establishing current good manufacturing practices for dietary supplements in June 2007.[39] Manufacturers will be required to conduct quality control activities to ensure the "identity, purity, quality, strength, and composition of dietary supplements."[39] Supplements that fail to meet quality standards will be considered misbranded or adulterated. Whether or not the new rule on good manufacturing practices can ensure high-quality supplements remains to be seen.

CONCLUSIONS

OAA Nutrition Program participants are older, are at higher nutritional risk, have lower incomes, and may have more-limited access to food than the general older population. Participants in home-delivered meal programs are even more vulnerable; they are frailer and have more functional impairments resulting from nutrition-related diseases and conditions.[1] MVMs can help fill intake gaps for some, but not all, vitamins and minerals. Evidence of health benefits and safety of supplement use among older adults with multiple health problems and medications, however, is insufficient to recommend the indiscriminate distribution of MVMs to OAA Nutrition Program participants.

A scientifically sound, safer strategy to address micronutrient inadequacies among older adults is to increase offerings of nutrient-dense foods and to expand access to nutrition services (i.e., screening, assessment, education, and counseling provided by registered dietitians). A decision to recommend an MVM and the types and amounts of nutrients to supplement must be individualized, with dietary intake, health status, and medication use taken into account. Those determined to need an MVM should take an appropriate one daily, not only on days they receive a program meal.

Food sources of nutrients remain the ideal way to improve nutrition intakes and meet the OAA goals. MVMs are not a one-size-fits-all quick fix for poor diets because they do not address the poor intakes of energy, protein, essential fatty acids, and fiber that may also result from inadequate food intake. Because OAA Nutrition Program meals typically provide more than half of participants' daily intakes of many nutrients, it is more important that nutrient-dense foods be incorporated into meals to best meet the needs of vulnerable older adults. Doing so requires nutrition and food-service expertise.

Positive health outcomes relate more to food intake patterns than to intakes of specific nutrients.[40] Nutritious, culturally appropriate OAA Nutrition Program meals provide more than a source of nutrients; they offer psychological and social benefits as well. Diverting funds from food to MVMs could undermine the program's goals of reducing hunger and food insecurity, promoting socialization, and enhancing the health and well-being of older adults[6] and could challenge the foundation of federal nutrition policy.

Screening for malnutrition risk and appropriate nutrition assessments and interventions—including additional meals and, if appropriate, dietary and liquid nutritional supplements—should be an integral part of evidence-based, consumer-directed care.[41] If, as a nation, we are serious about enabling older Americans to remain in their homes and communities and enhancing their quality of life, food and nutrition services cannot be taken for granted or corrected by a one-size-fits-all, quick-fix pill. ■

About the Authors

At the time of the study, Melissa Ventura Marra and Nancy S. Wellman were with the National Resource Center on Nutrition, Physical Activity & Aging, Stempel School of Public Health, Florida International University, Miami.

Requests for reprints should be sent to Melissa Ventura Marra, PhD, RD, National Resource Center on Nutrition, Physical Activity & Aging, Florida International University, Miami, FL 33199 (e-mails: melissa marra@comcast.net and wellman@fiu.edu).

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Contributors

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