

# Recommendations Abstracted from the American Geriatrics Society Consensus Statement on Vitamin D for Prevention of Falls and Their Consequences

*American Geriatrics Society Workgroup on Vitamin D Supplementation for Older Adults<sup>1</sup>*

The goal of this Consensus Statement is to help primary care practitioners achieve adequate vitamin D intake from all sources in their older patients, with the goal of reducing falls and fall-related injuries. The workgroup graded the quality of evidence and assigned an evidence level using established criteria. Based on the evidence for fall and fracture reduction in the clinical trials of older community-dwelling and institutionalized persons and meta-analyses, the workgroup concluded that a serum 25 hydroxyvitamin D (25(OH)D) concentration of 30 ng/mL (75 nmol/L) should be a minimum goal to achieve in older adults, particularly in frail adults, who are at higher risk of falls, injuries, and fractures. The workgroup concluded that the goal—to reduce fall injuries related to low vitamin D status—could be achieved safely and would not require practitioners to measure serum 25(OH)D concentrations in older adults in the absence of underlying conditions that increase the risk of hypercalcemia (e.g., advanced renal disease, certain malignancies, sarcoidosis).

Vitamin D is vital for the optimal function of numerous physiological systems. It is produced in the skin by exposure to ultraviolet B (UVB) light in sunlight. It is then hydroxylated in the liver to 25 hydroxyvitamin D (25(OH)D), a storage form of the vitamin and the measured indicator of vitamin D functional status. The active metabolite, 1,25-dihydroxyvitamin D<sub>3</sub>, is produced through further hydroxylation of 25(OH)D by 1- $\alpha$ -hydroxylase in the kidneys and other organs. Supplements, skin exposure to sunlight, and diet are all sources of

vitamin D. In the United States, milk, cereal, and some orange juice and bread are fortified with the vitamin. Despite these multiple sources, adults in the United States are at marked risk of low vitamin D levels.<sup>1</sup>

Serum concentrations less than 30 ng/mL (<75 nmol/L) have been associated with balance problems,<sup>2,3</sup> impaired lower extremity function,<sup>4</sup> high fall rates,<sup>5,6</sup> low bone mineral density (BMD),<sup>7</sup> and muscle weakness.<sup>8–10</sup> Significantly fewer falls and their consequences has been reported in association with greater vitamin D input.<sup>11,12</sup>

This summary presents important points from a full-length document and includes a minimal reference list. The full-length document, the *American Geriatrics Society Consensus Statement on Vitamin D for Prevention of Falls and Their Consequences*, can be found online at [www.geriatricscareonline.org](http://www.geriatricscareonline.org).

## OBJECTIVES

The objectives were to:

- 1) Develop clinical guidance for healthcare providers, including primary care physicians, internists, geriatricians, nurse practitioners, and other clinicians and policy-makers involved in providing health care for older adults, to achieve adequate vitamin D intake from all sources in their older patients, with the goal of reducing falls and fall-related injuries.
- 2) Establish optimal goals for 25(OH)D serum concentrations for reducing the risk of falls, injuries, and fractures in frail adults.
- 3) Define the best strategies for achieving optimal 25(OH)D serum levels in older adults.
- 4) Develop a series of statements that will offer a clear vitamin D intake guide for primary care practitioners caring for older people.
- 5) Identify at-risk groups of older adults and suggest relevant approaches to maximize vitamin D levels in these groups.
- 6) Assess current options for assessment of vitamin D serum levels.

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## EVIDENCE

The American Geriatrics Society convened a workgroup composed of researchers and clinicians with expertise and interest in vitamin D and older persons. The National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention (CDC) supported the project. Workgroup members collected and reviewed all meta-analyses published before 2008 and the randomized controlled trials (RCTs) cited in these meta-analyses. A Medline literature search was also conducted of all meta-analyses and RCTs published between January 2006 and February 2009, following a previously developed research strategy.<sup>13</sup> Workgroup members evaluated the evidence based on the Grading of Recommendations Assessment, Development, and Evaluation system.<sup>14</sup>

In November 2010, the Institute of Medicine issued a report, *Dietary Reference Intakes for Calcium and Vitamin D*, focusing on providing public health recommendations to the U.S. Food and Drug Administration (FDA) for food labeling.<sup>15</sup> After the report was released, the workgroup again reviewed the evidence and reformatted the recommendations into two sections of consensus statements. Section 1 statements consist of recommendations to reduce falls and fractures. Section 2 presents strategies for optimizing vitamin D status.

A detailed description of the search methods appears in the full-length document posted online.

## COSTS, BENEFITS, AND HARM

The economic and societal effect of fall injuries, coupled with the aging of the U.S. population, makes fall prevention a significant public health concern. In 2010, the direct medical costs of falls in older adults were estimated to be \$28.2 billion, after adjusting for inflation.<sup>16</sup> Fewer falls may result in better quality of life and fewer fractures and other injuries, reducing costs to institutions. Delaying the loss of mobility and decline in activities of daily living that accompany falls and fractures will reduce the time and the burden of direct care in the institutional setting.

## VALIDATION

The American College of Physicians, American Academy of Orthopaedic Surgeons, American College of Clinical Pharmacy, American College of Obstetricians and Gynecologists, American Geriatrics Society, American Medical Directors Association, American Osteopathic Association, American Society for Bone and Mineral Research, American Society of Nutrition, International Society for Clinical Densitometry, National Osteoporosis Foundation, and The Endocrine Society provided peer review of a preliminary draft of this guideline.

### SECTION 1. Recommendations to Reduce Falls and Fractures in Older People

**STATEMENT 1a:** Clinicians are strongly advised to recommend vitamin D supplementation of at least 1,000 international units (IU)/d, as well as

calcium supplementation, to community-dwelling older adults ( $\geq 65$ ) to reduce the risk of fractures and falls.

This minimum daily supplement of 1,000 IU takes into account two major factors. First, many subjects in the vitamin D supplement groups of cited trials had 25(OH)D serum concentrations below recommended levels. Second, dosages less than 600 IU did not prevent falls.

**STATEMENT 1b:** There are insufficient data at this time to support a recommendation for increased vitamin D supplementation without calcium for older persons residing in the community or in institutional settings.

*Calcium:* In most trials, calcium dosages ranged between 500 and 1,200 mg/d, with 1,000 to 1,200 mg/d most commonly prescribed.

**STATEMENT 2:** Clinicians are strongly advised to recommend vitamin D supplementation of at least 1,000 IU/d with calcium to older adults residing in institutionalized settings to reduce the risk of fracture and falls.

### SECTION 2. Strategies for Optimizing Vitamin D Status

A serum 25(OH)D concentration of 30 ng/mL (75 nmol/L) should be a minimum goal for older adults, particularly for frail adults, who are at higher risk for falls, injuries, and fractures.

**STATEMENT 3:** Clinicians should review older adults' vitamin D intake from all sources (diet, supplements, sunlight) and discuss strategies to achieve a total vitamin D input associated with fall and fracture prevention.

The workgroup agreed on two strategies to ensure that 92% of older adults would achieve serum 25(OH)D levels of greater than 30 ng/mL (75 nmol/L):

*Recommend an average daily input from all sources of 4,000 IU for all older adults.* This level of vitamin D input should result in approximately 92% of older adults in the United States achieving target 25(OH)D levels regardless of skin pigmentation, obesity, or sun exposure (Table 1).

*Individualize supplementation levels with adjustments for sun exposure, skin pigmentation, and high body mass or obesity.* Table 2 provides suggestions for clinicians who wish to individualize vitamin D supplementation plans for their patients. The adjustments should be considered approximate estimates.

Current guidelines for prevention of skin cancer and aging of the skin should be the determining factor in advice given to the individual.

**STATEMENT 4a:** Routine laboratory testing for 25(OH)D serum concentrations before supplementation begins is not necessary.

**STATEMENT 4b:** It is not necessary for clinicians to routinely monitor 25(OH)D for safety or efficacy when supplementation is within the recommended limits.

**Table 1. Estimated 25 Hydroxyvitamin D (25(OH)D) Concentrations in Adults Aged 70 and Older Based on Estimate of Average Daily Vitamin D Intake Using the Institute of Medicine (IOM) Dose-Response Equation**

Predicted 25(OH)D Level (nmol/L)	Total Vitamin D Intake, Average Daily IU, Excluding Sun Exposure						
	1,000	1,500	2,000	2,500	3,000	3,500	4,000
Mean	75	80	83	85	87	89	90
Lowest (5th) percentile	53	56	59	60	62	63	64
Highest (95th) percentile	98	104	108	111	114	116	118
Population achieving $\geq 75$ nmol/L, %	51	65	74	79	83	85	92

Adapted from IOM calculation of dose response for adults aged  $\geq 70$ .<sup>15</sup>

**Table 2. Estimation of Individualized Vitamin D Supplementation**

Clinical Review	Adjustment	Calculation
Baseline supplement needs		
Starting supplement dose	3,000 IU/d	3,000 IU
Food input (Table 1)	Subtract estimated input of vitamin D from food	- IU
For most older adults, food input is small. Average input from food in U.S. adults = 150–225 IU/d		
Daily multivitamins with or without calcium and vitamin tablets	Subtract total daily vitamin D units	- IU
Unprotected sun exposure <sup>a</sup>	During summer months only, subtract 500–1,000 IU/d with regular unprotected sun exposure during summer months*	- IU
NOT recommended as a strategy: If exposure is uncertain, do not adjust supplement dose. Do not adjust for institutionalized residents. Adjust dose only if individual has unprotected sun exposure (in bathing suit or shorts and short sleeved shirt) for 15 minutes in sun several days per week.		
Obesity or high body mass (>90 kg) is associated with lower vitamin D levels and ~20% lower 25(OH)D response to supplementation. <sup>17,18</sup>	Add 500–800 IU/d	+ IU
Skin pigmentation <sup>19</sup> Mexican Americans and African Americans have lower vitamin D levels than non-Hispanic whites.	Add 300–600 IU/d	+ IU
Total additional supplement dose per day Do not exceed 4,000 IU/d except in cases of special populations (see below). See Statements 5 and 6 to determine choice of vitamin D2 or D3 formulation based on patient preference of frequency of supplementation.		
<b>Special Populations:</b>		
For special populations, monitoring serum 25(OH)D levels may be useful in helping to verify adjusted dose.		
<b>Medications</b>		
Agents that bind vitamin D in the gut (e.g., cholestyramine)		
Agents that accelerate the breakdown of vitamin D (e.g., inducers of the cytochrome P450 pathway such as phenytoin and phenobarbital)	Increase dose according to serum 25(OH)D	
Malabsorption syndromes	Increase dose according to serum 25(OH)D	

<sup>a</sup> This sun exposure adjustment is explicitly not a recommendation for extended, unprotected sun exposure as a strategy to achieve adequate vitamin D serum levels. Current guidelines for prevention of skin cancer and aging of the skin should be the determining factor in advice given to the patient.

Projected levels of the top 5% of individuals on 4,000 IU total intake are 47 ng/mL (118 nmol/L). These levels are well below the lowest levels associated with toxicity (60 ng/mL) (150 nmol/L).

In the average person, there is no need to “clinically manage” vitamin D by repeated laboratory testing. Based on all available valid toxicity studies, an input of 4,000 IU/d of vitamin D from all sources is considerably below the proposed upper tolerable level of 10,000 IU/d.<sup>20</sup>

**STATEMENT 4c:** If clinicians choose to monitor 25(OH)D, they are advised to test after 4 months of vitamin D3 supplementation to confirm that appropriate levels have been achieved.

Samples should be obtained at approximately the mid-point between doses. This will give the best estimate of the average concentration between doses.<sup>21</sup>

Monitoring should be considered and may be advisable in the following settings (Table 2):

- 1) Individuals taking medications that bind vitamin D in the gut or accelerate the breakdown of vitamin D (e.g., cholestyramine, inducers of the cytochrome P450 pathway such as phenytoin and phenobarbital)
- 2) Obesity (body mass index  $>30 \text{ kg/m}^2$  or body mass  $>90 \text{ kg}$ )
- 3) Malabsorption syndromes
- 4) Individuals who limit their vitamin D intake from all sources below recommended intake

If vitamin D monitoring is considered necessary, 25(OH)D measurement is the preferred choice.

If there is a concern about the safety of vitamin D supplementation or treatment, the important diagnostic indicators are circulating calcium concentration and urine calcium excretion.

**STATEMENT 5:** Because of the different pharmacokinetic profiles of vitamin D2 and vitamin D3, clinicians should recommend vitamin D3 supplementation intervals of 4 months or less and vitamin D2 supplementation intervals of 14 days or less.

Clinicians should not recommend large bolus doses of vitamin D2 or D3 ( $\geq 300,000 \text{ IU}$ ).

The pharmacokinetic properties of vitamins D2 and D3 differ, with more-consistent and higher serum concentrations of 25(OH)D associated with vitamin D3 supplementation. Because longer intervals between doses of vitamin D2 will result in large fluctuations of serum 25(OH)D concentrations, the dosing interval with vitamin D2 should not exceed 14 days. Annual doses of vitamin D2 or D3 in autumn or winter are not recommended. (The term “calciferol” on a preparation refers to vitamin D2 and cholecalciferol to vitamin D3.)

### D3 Supplementation

Vitamin D3 is available as nonprescription, over-the-counter products in dosages of 400, 800, 1,000, 2,000, 5,000, and 10,000 IU. A 50,000-IU formulation is currently available online. Vitamin D2 is available in a prescription form of 50,000 IU. This high-dose formulation of D2 is more expensive but may be more readily available at retail pharmacies. Vitamin D is also available in multivitamin preparations, in calcium supplements, in foods fortified with the vitamin, and in cod liver oil, but practitioners should be aware that the FDA has not approved use of the prescription product at 50,000 IU vitamin D2 per dose to influence serum 25(OH)D levels and that this is an off-label use of the drug.

Efforts to achieve adequate supplemental doses of vitamin D through cod liver oil exposes the individual to vitamin A levels associated with greater risk of osteoporosis, hip fracture, and malignancies.

Administration of vitamin D in combination pills containing calcium supplements is not recommended as a *primary* strategy for achieving adequate vitamin D intake because of the requirement for repeated daily dosing, low maximum vitamin D intake from calcium pills, and high rates of nonadherence to calcium supplements.

Vitamin D should not be given with steroid-binding resins (cholestyramine), high-fiber cereals (oatmeal and bran

flakes), and fiber stool softeners. Taking vitamin D with meals containing oils is thought to enhance absorption.

Vitamin D gel capsules contain various vegetable oils acting as a vehicle. Some individuals are allergic to these oils and react with symptoms such as diarrhea or, occasionally, rash. This allergic reaction may necessitate a switch to a different product formulation. (Updates regarding available formulations are published at the American Geriatrics Society website: [www.AGS.org](http://www.AGS.org).)

Vegetarians who choose not to use vitamin D3 because of its animal derivation (from lanolin, the oil obtained from sheep’s wool) should be advised to take vitamin D2. People who follow kosher dietary law are permitted to consume vitamin D3 or D2. Vitamin D3 is considered halal if the source is confirmed to be derived from wool sheared from live sheep.

**STATEMENT 6:** Because vitamin D3 supplements given daily, weekly, or monthly are equally effective at achieving target serum concentrations, physicians should discuss with their patients which supplementation schedule will achieve the best adherence.

Clinicians should discuss calcium adherence with patients before prescribing combination pills of calcium plus vitamin D. In some cases, the combination of a monthly high-dose capsule and a combination calcium–vitamin D pill may be an effective strategy. For other people, adherence to vitamin D supplementation may be better if daily supplements are not required.

### DISCUSSION

The workgroup chose the 4,000-IU input from all sources for the following reasons.

In clinical practice, it is likely that adherence to supplementation will be lower than in clinical trials that have demonstrated fall and fracture reduction with vitamin D supplementation.

The vast majority of older adults in the United States will require higher supplementation to achieve minimum desirable levels. Based on calculations from the Institute of Medicine’s 2011 publication, “Dietary reference intakes for calcium and vitamin D’s dose response estimates,” only approximately half of adults aged 70 and older will achieve a 25(OH)D blood level of 30 ng/mL (75 nmol/L) with a daily supplement of 1,000 IU.<sup>15</sup>

Given the realities of variable adherence to clinician recommendations and the wide safety margin of vitamin D supplements, the workgroup made the recommendation for vitamin D supplementation of at least 1,000 IU (average daily supplement) to reduce falls and fractures. For persons without underlying conditions that increase the risk of hypercalcemia (e.g., advanced renal disease, certain malignancies, sarcoidosis), there is no known risk from taking a 1,000-IU vitamin D supplement per day. Individuals with advanced renal failure and sarcoidosis are not covered in this guideline. Although there is no evidence that age alone is a risk factor for low vitamin D levels, lack of exposure to sunlight in long-term care settings and reduction in 7-dehydrocholesterol levels in the skin are associated with lower vitamin D levels in older people.<sup>22</sup>



The workgroup conclusions differed from those of the Institute of Medicine report, *Dietary Reference Intakes for Calcium and Vitamin D*, which stated that there was no benefit to 25(OH)D above 20 ng/mL (50 nmol/L) in older adults.<sup>15</sup> A simple visual review of the individual trials showed that four trials with serum levels of 24 ng/mL (60 nmol/L) or greater demonstrated lower fall rates. The three trials with serum levels below 25 ng/mL (60 nmol/L) all had higher relative risk for falls. In studies that demonstrated fewer falls and fractures, the average concentrations of 25(OH)D achieved were consistently greater than 26 ng/mL (65 nmol/L). Point estimates of risk reduction were greater in studies with the highest 25(OH)D concentrations achieved.<sup>11,23–25</sup> In these randomized clinical trials, approximately half of the subjects in the vitamin D supplement groups had 25(OH)D serum concentrations below the levels recommended for musculoskeletal health. The workgroup concluded that higher supplement doses and serum levels of 25(OH)D of 25 ng/mL (60 nmol/L) or greater provide protection.

The target level recommended ( $\geq 30$  ng/mL, 75 nmol/L) is a physiologically conservative estimate. Outdoor summer workers typically achieve serum concentrations of twice that level.<sup>21</sup> Assuming that the additional supplemental inputs recommended are adhered to, the highest level reached will not exceed 60 ng/mL (150 nmol/L), which is still well below toxicity levels, even in the 5% of older adults with the highest baseline vitamin D levels, who are already in the recommended range. There are no recorded cases of vitamin D intoxication at serum levels less than 200 ng/mL (500 nmol/L) or at oral inputs less than 30,000 IU/d.<sup>20</sup>

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