### **U.S. Preventive Services Task Force**

## Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Older Adults: Recommendation Statement

## Summary of Recommendations and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of vitamin D and calcium supplementation, alone or combined, for the primary prevention of fractures in men and premenopausal women (*Table 1*). **I statement.** 

The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of daily supplementation with dosages greater than 400 IU of vitamin D and greater than 1,000 mg of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women. I statement.

The USPSTF recommends against daily supplementation with 400 IU or less of vitamin D and 1,000 mg or less of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women. **D recommendation.** 

See the Clinical Considerations section for suggestions for practice regarding the I statements.

These recommendations apply to community-dwelling, asymptomatic adults. "Community-dwelling" is defined as not living in a nursing home or other institutional care setting. These recommendations do not apply to persons with

a history of osteoporotic fractures, increased risk for falls, or a diagnosis of osteoporosis or vitamin D deficiency.

#### **Rationale**

#### **IMPORTANCE**

Approximately 2 million osteoporotic fractures occurred in the United States in 2005.<sup>1,2</sup> Within 1 year of experiencing a hip fracture, many patients are unable to walk independently, more than half require assistance with activities of daily living, <sup>3,4</sup> and 20% to 30% of patients will die.<sup>5</sup>

#### BENEFITS OF PREVENTIVE MEDICATION

The USPSTF found inadequate evidence to determine the effects of vitamin D and calcium supplementation, alone or combined, on the incidence of fractures in men and premenopausal women. The USPSTF found adequate evidence that daily supplementation with 400 IU or less of vitamin D combined with 1,000 mg or less of calcium has no effect on the incidence of fractures in community-dwelling, postmenopausal women. The USPSTF found inadequate evidence regarding the effects of higher doses of vitamin D and calcium supplementation, alone or combined, on the incidence of fractures in community-dwelling, postmenopausal women.

See related Putting Prevention into Practice on page 253.

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**This summary** is one in a series excerpted from the Recommendation Statements released by the USPSTF. These statements address preventive health services for use in primary care clinical settings, including screening tests, counseling, and preventive medications.

The complete version of this statement, including supporting scientific evidence, evidence tables, grading system, members of the USPSTF at the time this recommendation was finalized, and references, is available on the USPSTF website at https://www.uspreventiveservicestaskforce.org/.

This series is coordinated by Kenny Lin, MD, Deputy Editor.

**A collection** of USPSTF recommendation statements published in *AFP* is available at https://www.aafp.org/afp/uspstf.

# Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Adults: Clinical Summary of the USPSTF Recommendations

Population	Men and premeno- pausal women	> 400 IU of vitamin D and > 1,000 mg of calcium in postmeno- pausal women	≤ 400 IU of vitamin D and ≤ 1,000 mg of calcium in postmeno- pausal women	
Recommendation	No recommendation. Grade: I (insufficient evidence)	No recommendation. Grade: I (insufficient evidence)	Do not recommend. Grade: D	
Risk assessment	Low bone mass, older age, and history of falls are major risk factors for incident osteoporotic fractures. Other risk factors for low bone mass and fractures include female sex, smoking, use of glucocorticoids, and use of other medications that impair bone metabolism (e.g., aromatase inhibitors). Absolute fracture risk is very low in premenopausal women compared with postmenopausal women.			
Preventive medication	The recommendation against supplementation at lower doses was based on an overall assessment that supplementation at low doses provides no benefit. Evidence on the effect of supplementation on fractures at higher doses is conflicting, with some studies showing a reduction in certain fractures at higher doses and others showing no reduction or even an increase. More studies are needed to more clearly determine whether supplementation with vitamin D, calcium, or both consistently prevents fractures. If future evidence shows a benefit, the magnitude of that benefit will need to be weighed against the magnitude of harms caused by supplementation (kidney stones).			
Other relevant USPSTF recommendations	The USPSTF recommends against vitamin D supplementation to prevent falls in community-dwelling adults 65 years or older. The USPSTF recommends exercise interventions to prevent falls in community-dwelling older adults at increased risk for falls; multifactorial interventions may also be effective in some persons as well. The USPSTF recommends screening for osteoporosis in women 65 years or older and in younger women at increased risk. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults.			

**Note:** For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, go to https://www.uspreventiveservicestaskforce.org/.

USPSTF = U.S. Preventive Services Task Force.

#### HARMS OF PREVENTIVE MEDICATION

The USPSTF found adequate evidence that supplementation with vitamin D and calcium increases the incidence of kidney stones. The USPSTF assessed the magnitude of this harm as small. The USPSTF found a few studies evaluating supplementation with vitamin D alone that suggested no increase in incident cardiovascular disease.

#### **USPSTF ASSESSMENT**

Community-Dwelling, Postmenopausal Women. The USPSTF concludes that the evidence on the benefit of daily supplementation with dosages greater than 400 IU of vitamin D and greater than 1,000 mg of calcium for the primary prevention

of fractures in community-dwelling, postmenopausal women is lacking, and the balance of benefits and harms cannot be determined.

The USPSTF concludes with moderate certainty that daily supplementation with 400 IU or less of vitamin D and 1,000 mg or less of calcium has no net benefit for the primary prevention of fractures in community-dwelling, postmenopausal women.

Men and Premenopausal Women. The USPSTF concludes that the evidence on the benefit of vitamin D and calcium supplementation, alone or combined, for the primary prevention of fractures in men and premenopausal women is lacking, and the balance of benefits and harms cannot be determined.

#### **Clinical Considerations**

## PATIENT POPULATION UNDER CONSIDERATION

These recommendations apply to community-dwelling, asymptomatic adults. "Community-dwelling" is defined as not living in a nursing home or other institutional care setting. These recommendations do not apply to persons with a history of osteoporotic fractures, increased risk for falls, or a diagnosis of osteoporosis or vitamin D deficiency.

## SUGGESTIONS FOR PRACTICE REGARDING THE I STATEMENTS

Potential Preventable Burden. Approximately 2 million osteoporotic fractures occurred in the United States in 2005.<sup>2</sup> The health burden of fractures is substantial in the older adult population. Twenty percent to 30% of patients die within 1 year of a hip fracture, with significantly higher mortality rates in men than in women.<sup>5</sup> Nearly 40% of persons who experience a fracture are unable to walk independently at 1 year, and 60% require assistance with at least 1 essential activity of daily living.<sup>3,4</sup>

Low bone mass, older age, and history of falls are major risk factors for incident osteoporotic fractures.<sup>1,6</sup> Ten percent to 15% of falls result in fractures,6 and nearly all hip fractures are related to a fall.7 Other risks factors for low bone mass and fractures include female sex, smoking, use of glucocorticoids, and use of other medications that impair bone metabolism (e.g., aromatase inhibitors).8-11 Most fractures (71%) occur among women,<sup>2</sup> and an estimated 74% of all fractures that occur in women are among those 65 years or older.6 Although the risk for fractures in premenopausal women increases with lower peak bone mass, absolute fracture risk in premenopausal women is very low compared with that in postmenopausal women.<sup>12</sup> Although fractures occur more frequently in women, mortality rates after a hip fracture are significantly higher in men than in women.<sup>2,13</sup>

The large Women's Health Initiative (WHI) trial (n = 36,282), which studied daily supplementation with 400 IU of vitamin  $D_3$  (cholecalciferol) and 1,000 mg of calcium, reported no significant reduction in any fracture outcome<sup>14</sup>; thus, the USPSTF concluded that supplementation with 400 IU or less of vitamin D and 1,000 mg or less of calcium does not prevent fractures. Studies of supplementation with higher doses of vitamin

D and calcium (alone or combined) showed inconsistent results and were frequently underpowered to detect differences; thus, the USPSTF concluded that the evidence on supplementation with higher doses of vitamin D and calcium to prevent fractures is inadequate.

#### **POTENTIAL HARMS**

The WHI trial found a statistically significant increase in the incidence of kidney stones in women taking vitamin D and calcium compared with women taking placebo. For every 273 women who received supplementation over a 7-year follow-up period, I woman was diagnosed with a urinary tract stone. In addition, a recent study of combined vitamin D and calcium supplementation found findings consistent with those from the WHI trial, although the increase was not statistically significant. Another recent study found no increase in incident cardiovascular disease with high-dose vitamin D supplementation.

In a separate recommendation statement, <sup>18</sup> the USPSTF found that vitamin D supplementation does not reduce the number of falls or the number of persons who experience a fall. A single study suggested that an annual high dose of vitamin D (500,000 IU) may even be associated with a greater number of injurious falls and a greater number of persons experiencing falls and fractures. <sup>19</sup> The USPSTF now recommends against vitamin D supplementation to prevent falls in community-dwelling older adults. <sup>18</sup>

#### **CURRENT PRACTICE**

Vitamin D and calcium supplementation are often recommended for women, especially postmenopausal women, to prevent fractures, although actual use is uncertain. Based on 2011-2012 data from the National Health and Nutrition Examination Survey, an estimated 27% of men and 35% of women older than 20 years take a vitamin D supplement, and 26% of men and 33% of women take a calcium supplement.<sup>20</sup> The exact dosage of supplementation is not known.

#### OTHER APPROACHES TO PREVENTION

The USPSTF recommends screening for osteoporosis in women 65 years or older and in younger women at increased risk.<sup>21</sup> The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults.<sup>22</sup>

#### **USPSTF**

The USPSTF recently updated its recommendation on interventions to prevent falls in community-dwelling older adults. The USPSTF assessed the effect of vitamin D to prevent falls in older adults at average and increased risk for falls without vitamin D insufficiency or deficiency. The USPSTF found adequate evidence that vitamin D supplementation does not prevent falls. The USPSTF also found that exercise can prevent falls in community-dwelling older adults at increased risk for falls; multifactorial interventions may also be effective in some persons as well. 18,19

**This recommendation** statement was first published in *JAMA*. 2018;319(15):1592-1599.

The "Other Considerations," "Discussion," "Update of Previous USPSTF Recommendation," and "Recommendations of Others" sections of this recommendation statement are available at https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/vitamin-d-calcium-orcombined-supplementation-for-the-primary-prevention-of-fractures-in-adults-preventive-medication.

**The USPSTF** recommendations are independent of the U.S. government. They do not represent the views of the Agency for Healthcare Research and Quality, the U.S. Department of Health and Human Services, or the U.S. Public Health Service.

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