

FINAL Key Questions and Background

Screening and Monitoring Tests for Osteopenia/Osteoporosis

Introduction

Osteoporosis is a systemic skeletal condition characterized by both low bone mass and deteriorating bone quality, resulting in an increased risk of fracture. Primary osteoporosis occurs without a known cause. One estimate suggests a lifetime risk of osteoporotic fracture of 50% for Americans over the age of 50, with women being at higher risk than men. Fractures in this population are associated with higher mortality and diminished function and quality of life (QOL). Various classes of medications have been found to be effective in correcting or preventing osteoporosis.

Osteoporosis is diagnosed when a fragility (nontraumatic) fracture occurs or bone mineral density (BMD) measured by dual-energy x-ray absorptiometry (DXA) is found to be outside the normal distribution in young health individuals. DXA is used to obtain measures of BMD, typically in the femoral neck (hip) and lumbar spine. An alternative method of bone measurement is quantitative ultrasonography (QUS), which measures bone *quality*, and typically is used for peripheral measurements such as in the calcaneus (heel). DXA and QUS have been shown to perform comparably well in predicting hip or vertebral fracture. However, standard diagnostic criteria for osteoporosis as well as patient selection in studies of osteoporosis medications are based on DXA scores, not on QUS scores, which do not correlate strongly with DXA scores. Other emerging technologies for assessing BMD include quantitative computed tomography (QCT) and dual photon absorptiometry (DPA), but diagnostic criteria and treatment guidelines are based on BMD as measured by DXA. Practice guidelines recommend screening with DXA.

Numerous methods have been validated for predicting low BMD and for predicting fracture. A 2010 evidence review conducted for the Agency for Healthcare Research and Quality (AHRQ) found that simple and complex methods perform similarly.

Policy Context

In 2011, the U.S. Preventive Services Task Force (USPSTF) issued updated recommendations on screening for osteoporosis, taking into account two systematic evidence reviews prepared by or for, the AHRQ in 2002 and 2010.

The following are current USPSTF recommendations:

- Screening for osteoporosis should be conducted in women aged ≥ 65 years without previous known fractures or secondary causes of osteoporosis. (Grade B recommendation)
- Screening for osteoporosis should be conducted in women aged < 65 years whose 10-year fracture risk is equal to or greater than that of a 65-year-old white woman without additional risk factors. (Grade B recommendation)

- No recommendation may be made for men who have no previous known fractures or secondary causes of osteoporosis. (Grade I for insufficient evidence).

Regarding the optimal interval for screening, the USPSTF has no formal recommendation but advises that a minimum of two years may be needed to reliably measure a change in BMD and that longer intervals may be necessary to improve fracture risk prediction.

In 2013 the Oregon Health Evidence Review Commission (OR HERC) issued guidance that mirrors the USPSTF recommendations for initial screening in men and women. The guidance statement also recommends that screening should not be repeated more often than every 15 years for women with normal BMD, every 4 years for women with moderate osteopenia, and every 2 years for women with advanced osteopenia or osteoporosis. The recommendations for repeat screening are based on a recently published population-based study designed to address this issue. The OR HERC guidance document did not cite any new evidence pertaining to screening in men.

An analysis of the evidence supporting these public health and policy statements and the most recently published evidence can help promote the most efficient use of osteoporosis screening for beneficiaries of Washington Health Care Authority (HCA) plans. Additionally, an analysis of the evidence regarding the benefits of treatment monitoring with BMD testing will permit a more comprehensive policy.

Scope of This HTA

Populations: Adult men and women.

Interventions: BMD testing with dual x-ray absorptiometry (DXA)**Comparators:** Clinical assessment of fracture risk without BMD testing

Outcomes: Health outcomes such as fractures, fracture-related morbidity, fracture-related mortality; intermediate outcomes such as clinical management decisions and patient behavior; measures of test performance such as accuracy and diagnostic yield; harms associated with screening and with osteoporosis medications; cost and cost-effectiveness.

Key Questions

1. Is there direct evidence that screening for osteoporosis and low bone density improves health outcomes, clinical management decisions, or patient choices?
 - 1a. For individual patients, and do these outcomes vary according to age, sex, or other risk factors for BMD or fracture?
 - 1b. In populations, and do these outcomes vary by population characteristics?
2. Is there direct evidence that monitoring (serial testing) for osteoporosis and low bone density improves health outcomes, clinical management decisions, or patient choices:
 - 2a. For individual patients, and do these outcomes vary according to age, sex, other risk factors (including previous BMD measurements), treatment status, or testing interval?

- 2b. In populations, and do these outcomes vary according to population characteristics or testing interval?
- 2c. What is the minimum interval required to detect transition from normal or low BMD to osteoporosis or to assess treatment effect?
3. What is the number needed to screen (NNS) to prevent one fracture in subgroups defined by age, sex, and other risk factors?
4. Are bone density tests safe and what are the potential downstream adverse effects?
5. What are the costs and cost-effectiveness of osteoporosis screening and monitoring?

For more information about this technology review and the Washington State Health Technology Assessment program, visit www.hca.wa.gov/hta.