
Washington State Health Care Authority, HTA Program

Key Questions Vitamin D Screening and Testing

Introduction

HTA has selected Vitamin D Screening and Testing (Vitamin D) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on its safety, efficacy, and cost-effectiveness.

Vitamin D is a nutrient critical to human health. Vitamin D levels are influenced by diet, exposure to sunlight (ultraviolet radiation) and some disease processes. Testing for vitamin D requires a blood draw and laboratory assessment of levels. Vitamin D status may be related to numerous risk factors, conditions, and diseases. Testing might be performed for a variety of concerns including vitamin D insufficiency, risk of poor bone health, presence of conditions resulting in malabsorption or altered metabolism, and suspected toxicity.

Policy Context

There are questions about the accuracy and usefulness of tests for vitamin D levels, especially in healthy subjects. Assessing vitamin D levels may be useful to influence diagnostic or treatment decisions in some circumstances, though the usefulness of testing is uncertain in others.

Key questions guide the development of the evidence report. HTA seeks to identify the appropriate clinical topics (e.g., population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

PICO

Population: Healthy¹ populations: Generally healthy adults, including pregnant women, and children without symptoms or findings of the outcome of interest.

Populations with known disease that may be associated with vitamin D

¹ **Healthy**, as used here refers to absence of a disease known to cause vitamin D insufficiency, such as chronic kidney disease, and absence of a particular outcome disease of interest, e.g. individuals without a diagnosis of cancer when looking at the effect of vitamin D on risk of cancer.

insufficiency: Adults and children with chronic diseases such as poor bone health, obesity, cardiovascular disease (CVD) (e.g., hypertension, heart failure, coronary artery disease), cancer, diabetes, multiple sclerosis (MS), or depression.

Intervention: Serum vitamin D testing

Comparator: No testing

Outcomes: Healthy populations: Growth, obesity, bone health and fractures or falls; all-cause mortality; and the incidence of other chronic diseases such as of CVD, cancer, diabetes, MS, and depression, as well as related mortality.

Populations with known disease that may be associated with vitamin D insufficiency: Health outcomes related to the indication disease.

Key Questions

KQ1: Has a relationship between serum vitamin D and health outcomes been demonstrated and have clinically valid cutoff points for serum vitamin D measurement been defined (*clinical validity*)?

- a. In healthy populations
- b. In patients with chronic disease

KQ2: Is there evidence that testing for serum vitamin D levels improves health outcomes: (*clinical utility*)

- a. As a routine screening test in healthy patients?
- b. In patients who already have chronic disease thought to be associated with low serum vitamin D?

KQ3: Are there harms associated with vitamin D testing or with subsequent supplementation?

KQ4: What is the evidence of the differential clinical utility of vitamin D testing, considering the risk of low serum concentrations and clinical impact of supplementation doses in:

- a. Healthy populations?
- b. Populations who already have chronic disease, according to factors such as:

Patient characteristics

- i. Age or life stage
- ii. Race or ethnicity
- iii. Geographic location
- iv. Nutritional status, diet, or personal use of calcium/vitamin D supplements
- v. Lifestyle factors such as smoking
- vi. Obesity
- vii. Baseline serum vitamin D level
- viii. Baseline risk of the health outcome of interest

Testing parameters

- i. Assay used
- ii. Frequency of monitoring
- iii. Time of year

KQ5: What are the cost implications of vitamin D testing, including the cost-effectiveness of testing compared with not testing?

Public Comment and Response

See *Key Question Public Comment and Response* document published separately.

[For additional information on key questions and public comments](#)