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American Heart Association Position Statement on State Efforts to Mandate Coronary Arterial Calcification and Carotid Intima Media Thickness Screenings Among Asymptomatic Adults March 7, 2012

Heart disease is the leading cause of death in the United States in both men and women, accounting for nearly 25 percent of all deaths each year. Coronary heart disease (CHD), the most common type of heart disease, places an unnecessary burden on the United States healthcare system. In 2010 alone, CHD was projected to have cost the United States almost \$110 billion in increased health care services, medications, and lost productivity.

In an effort to reduce the high morbidity and heavy financial burden of CHD among their residents, four states have recently proposed or passed legislation mandating that health insurers offer coverage of certain imaging tests to screen asymptomatic adults for CHD risk. These tests include scans to determine the amount of coronary artery calcification (CAC) scans and the thickness of arterial walls by measuring carotid intima-media thickness (carotid IMT) ultrasound screenings, both of which are markers for CHD risk.

While identifying persons at increased risk of developing CHD is an important goal for the American Heart Association (AHA), these recent state efforts are currently not supported adequately with sufficient evidence to show that widespread screening of asymptomatic adults is clinically appropriate. The AHA will continue to evaluate the developing science in this area to to inform future policy efforts around population-based screening.

Until stronger and more granular evidence for the efficacy of coronary artery calcification (CAC) scans and carotid IMT ultrasound screenings for CHD in the asymptomatic adult population is established, the AHA does not support state efforts to mandate coverage for these CHD screening methods. Instead, AHA recommends that individual patients should discuss alternative guideline recommended CHD screening options with their physicians and make decisions that are consistent with the best available information based on the current science.

Screening for Coronary Heart Disease: Background

Coronary heart disease is a condition in which plaque builds up inside the coronary arteries that supply oxygen-rich blood to the heart. When plaque (which is made up of deposits of fat, cholesterol, calcium and other substances found in the blood) accumulates in the arteries, the condition is called atherosclerosis. Detecting whether an individual has atherosclerosis is an important goal of preventive cardiology. If individuals are aware of their risk of CHD before symptoms occur, they may be able to take preventive medications and make lifestyle changes to prevent the onset of CHD.

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Although there are guidelines on how to detect individuals at risk for CHD, two additional methods currently not recommended by guidelines are being recommended by some physicians to detect atherosclerosis in certain patients including:

- (1) Coronary Artery Calcification (CAC) Scanning: This test detects and quantifies the amount of calcification of the coronary arteries, a marker for atherosclerosis.
- (2) Carotid Intima Media Thickness (carotid IMT) Ultrasound: This screening measures the thickness of a patient's arterial walls and may detect atherosclerotic plaque. Increased thickness in the walls of the carotid artery is associated with risk for CHD.

While used by some physicians, these tests have not been shown to be clinically useful for screening asymptomatic patients at low or high risk of CHD. However, CAC scanning and carotid IMT ultrasounds may be valuable for patients who are considered to be at an intermediate-risk for CHD, as test results can be used to reclassify patients into a higher or lower risk status based on the results of these tests.^{3, 4, 5}

State Initiatives for CHD Screening

In June, 2009, Texas passed the *Texas Heart Attack Prevention Bill* mandating that health insurers offer coverage for CAC scanning and carotid IMT ultrasonography to detect early signs of CHD in asymptomatic adults. After the passage of the Texas legislation, similar bills have been proposed in Massachusetts, Florida, and Illinois.

These state initiatives require health insurance coverage of CAC scanning and carotid IMT ultrasounds for men aged 45–76 and women aged 55–76 who have additional risk factors for CHD (e.g. diabetes, high blood pressure, or high cholesterol) or are considered as intermediate or high-risk for CHD through previous risk assessment. While the state initiatives specifically address screening coverage for intermediate- and high-risk patients, they do not require coverage for low-risk individuals.

The Society for Heart Attack Prevention and Eradication (SHAPE)* and other supporters of these state initiatives reason that widespread screening of asymptomatic adults for coronary calcification and carotid artery thickness would detect greater numbers of individuals at high-risk for CHD, prompting these individuals to seek appropriate preventive treatment.

Evidence Does Not Support State Initiatives: AHA/ACCF Guidelines and USPSTF Recommendations

American Heart Association/American College of Cardiology Foundation Clinical Expert Consensus Document of Coronary Artery Calcium Scoring ("AHA/ACCF Consensus Document"). The AHA/ACCF Consensus Document, released in 2007, reviewed recent evidence on the prognostic value of CAC scanning in asymptomatic individuals. The report determined that while some asymptomatic patients considered at intermediate risk for CHD may benefit from CAC scanning, there is insufficient evidence that widespread screening of asymptomatic adults is clinically appropriate, citing two major reasons: ³

^{*} In 2006, the SHAPE Task Force, convened by the Association for Eradication of Heart Attack, issued guidelines for widespread screening of asymptomatic adults for CHD using CAC scanning and carotid IMT ultrasounds.

- <u>Insufficient evidence of efficacy</u> The AHA/ACCF reviewers did not find clinical evidence to support CAC scanning in high-risk patients. The report stated that high-risk patients are not reasonable candidates for CAC scanning because these patients should be "treated aggressively consistent with secondary prevention goals based on the current NCEP III guidelines and thus should not require additional testing, including CAC scoring, to establish this risk evaluation."
- <u>Insufficient evidence of cost-effectiveness</u> To determine cost-effectiveness of testing, there should be randomized-controlled studies that show screenings enhance quality of life, prolong life, or both. The AHA/ACCF reviewers did not find randomized-controlled studies that assessed cost-effectiveness of CAC screening in asymptomatic adults.³

The ACCF/AHA Task Force on Practice Guidelines: The AHA/ACCF Task Force issued a report in 2010 evaluating the evidence-base for guidelines for assessment of cardiovascular risk in asymptomatic adults, including the carotid IMT ultrasound. The report stated that "[m]easurement of carotid [IMT] is reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate risk (Class IIa, Level of Evidence B)." ⁵ Published recommendations on the required equipment, technical approach, and operator training and experience for performance of the test must be carefully followed to achieve high-quality results. ^{6,7,8} The AHA/ACCF Task Force did not recommend broader use of carotid IMT screening because there is insufficient evidence of the incremental value of carotid IMT and cost-effectiveness beyond that available from standard risk assessments. The ability to improve overall patient outcomes is not established.

<u>U.S. Preventive Services Task Force (USPSTF) Recommendations</u>: In 2009, USPSTF concluded that the evidence was "insufficient to assess the balance of benefits and harms" in using CAC scanning and carotid IMT ultrasounds for measuring CHD risk in asymptomatic individuals. The USPSTF recommends that clinicians continue to use traditional risk assessment until further evidence on these screening methods is developed.

Position of the American Heart Association

In accordance with the USPSTF recommendation and AHA/ACCF's evidence-based scientific guidelines, AHA does not support the routine use of CAC scanning or carotid ultrasonography beyond the limited benefit for individuals at intermediate-risk for CHD. Until stronger evidence is established of the efficacy of utilizing CAC scans and carotid ultrasounds for screening the asymptomatic adult population for CHD, the AHA does not support state efforts to mandate these CHD screening methods.

Detecting early signs of CHD in asymptomatic patients continues to be an important goal for the AHA, and we recommend that physicians discuss evidence-based screening options with their patients individually.

References:

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- ⁵ 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2010, 122:2748-276.
- ⁶ Stein JH, Korcarz CE, Hurst RT, et al. Use of carotid ultrasound to identify subclinical vascular disease and evaluate cardiovascular disease risk: a consensus statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force J Am Soc Echocardiogr 2008;21:93-111.
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- ⁹ U.S. Preventive Services Task Force, "Using Nontraditional Risk Factors in Coronary Heart Disease Risk Assessment: U.S. Preventive Service Task Force Recommendation Statement", October 2009. http://www.uspreventiveservicestaskforce.org/uspstf/uspscoronaryhd.htm.

³ Greenland, P. et al., "ACCF/AHA 2007 Clinical Expert Consensus Document on Coronary Artery Calcium Scoring by Computed Tomography in Global Cardiovascular Risk Assessment and in Evaluation of Patients with Chest Pain." 115 *Circulation* 402, 412 (January 12, 2007).

⁴ Nambi V, Chambless L, Folsom A, et al. Carotid intima-media thickness and the presence or absence of plaque improves prediction of coronary heart disease risk in the Atherosclerosis Risk in Communities (ARIC) study. *J Am Coll Cardiol* 2010;55:1600 –7.