PUBLICCITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

February 19, 2015

Robert C. Garrett
President and Chief Executive Officer
Hackensack University Health Network
30 Prospect Avenue
Hackensack, NJ 07601

Dear Mr. Garrett:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, strongly urges you to immediately terminate HackensackUMC at Pascack Valley's and Palisades Medical Center's partnerships and affiliations with Life Line Screening — as evidenced by the website for Life Line Screening[1] — for the following reasons:

(1) There is widespread consensus among medical experts that the primary package of four cardiovascular disease screening tests plus the screening test for osteoporosis advertised by Life Line Screening[2] is not appropriate for unselected, asymptomatic individuals in the general population and is more likely to cause harm than to provide benefit.

None of the current evidence-based guidelines issued by major medical professional organizations for the appropriate use of these five tests supports the type of widespread screening of unselected, asymptomatic individuals promoted and provided by Life Line Screening for any one of these tests individually, let alone together as a package (see Appendix for further elaboration).

(2) The promotion of this screening relies on fearmongering — scaring healthy individuals about their future health.

Life Line Screening, like many other companies offering health screening tests directly to consumers, seeks to prompt asymptomatic individuals — for whom screening for asymptomatic cardiovascular disease and osteoporosis is *not clinically indicated* — to undergo screening by using inappropriate direct-to-consumer (DTC) advertisements and solicitations that target consumer fear about having undetected, potentially life-threatening diseases (see Appendix for examples of fearmongering language used in the company's promotional materials).[3]

---

[1] Life Line Screening. Featured hospitals. http://www.lifelinescreeninghospitals.com/featured-hospitals/. Accessed February 17, 2015.
[2] Life Line Screening. Screening packages. http://www.lifelinescreening.com/What-We-Do/Screening-Packages. Accessed January 28, 2015.
[3] Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.

(3) For many people, false-positive test results from this screening can lead to unfounded anxiety and additional unnecessary, risky, and costly diagnostic procedures and treatment interventions.[4,5]

Because this screening is performed broadly on *unselected, predominantly asymptomatic populations* (i.e., those not at significant risk), many people will have false-positive test results. False-positive results can cause unfounded anxiety and lead to additional diagnostic procedures and treatments, exposing screened individuals to additional risk of physical harm without providing offsetting benefits.

In addition to physical and psychological harms, false-positive results from medically inappropriate screening tests also cause financial harms to the people screened and to others. Unnecessary costs are borne *directly* by the screened patients/consumers for the initial screening and for some of the unnecessary follow-up testing and treatment interventions. Additionally, *indirect* cost to the broader insured population results from insurance companies passing on the costs of superfluous follow-up testing and treatment via increased premiums.

(4) Screening unselected, asymptomatic people will lead to *overdiagnosis*, which occurs when individuals are diagnosed with conditions that will never cause symptoms or death.

Some individuals undergoing inappropriate screening will have certain true-positive abnormal results, leading to the diagnosis of conditions that will never cause symptoms or death, a problem known as overdiagnosis.[6] As with false-positive test results, overdiagnosis leads to unnecessary anxiety and unnecessary medical interventions. For example, imaging tests, such as the ultrasound cardiovascular disease screening tests offered by Life Line Screening, can detect abnormalities that for many people are minor and not destined to ever progress enough to cause symptoms or death; these people cannot benefit from treatment. In fact, they can only be harmed. When healthy people are systematically encouraged to get screened, overdiagnosis and the problems caused by it are made worse.[7]

(5) The promotion and provision of this screening is *unethical*.

First, it is exploitative for Life Line Screening to profit from the promotion of medically nonbeneficial testing through the use of misleading advertisements and solicitations that play on people's fear. Second, this screening violates the ethical principles of beneficence (the duty to promote good and act in the best interest of the patient and the health of society) and nonmaleficence (the duty to do no harm to patients).[8,9] Finally, direct-to-consumer promotional

[4] Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.
[5] Perry S. Buyer beware on 'direct-to-consumer' health screenings. March 21, 2012. *MinnPost.* http://www.minnpost.com/second-opinion/2012/03/buyer-beware-direct-consumer-health-screenings. Accessed January 14, 2015.
[6] Welch HG, Schwartz LM, Woloshin S. *Overdiagnosed: Making People Sick in the Pursuit of Health*. 1st ed. Boston, MA: Beacon Press; 2011: at *xiv*.
[7] *Ibid*. Page 44.
[8] Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med*. 2012;157(10):747-748.

materials for screening tests that fail to disclose published guidelines on recommended indications for these tests, as well as the risks of harm, violate the ethical principle of respect for persons and patient autonomy (the duty to protect and foster a patient's free, uncoerced choices).[10,11]

For these reasons, HackensackUMC at Pascack Valley's and Palisades Medical Center's partnerships with Life Line Screening do a great disservice to the communities that they serve and adversely impact public health more broadly. It is therefore imperative that you direct these institutions to sever their relationships with Life Line Screening and refrain from endorsing the company's heavily promoted, nonselective, community-wide cardiovascular disease and osteoporosis screening programs.

Of note, many institutions like yours responded positively to similar requests from Public Citizen. In particular, on June 19, 2014, we wrote letters to 20 hospitals and medical institutions that had partnered with HealthFair, another company that inappropriately promotes similar direct-to-consumer cardiovascular disease screening tests, urging them to immediately sever their relationship with the company.[12] Fifteen of the 20 institutions have informed either us or representatives of the news media that they have terminated or will be terminating their relationships with HealthFair. Public Citizen applauded these actions.

On August 11, 2014, the *Journal of the American Medical Association* published a Viewpoint article critical of hospital relationships with DTC disease screening companies.[13] The article — co-authored by Erik Wallace, M.D., Associate Dean for the Colorado Springs Branch of the University of Colorado School of Medicine; John Schumann, M.D., Interim President, University of Oklahoma-Tulsa; and Steven Weinberger, M.D., Executive Vice President and Chief Executive Officer of the American College of Physicians, the pre-eminent national organization of internists — concluded as follows:

> If the primary goal of hospitals and DTC screening companies is to improve the health of the populations they serve, then both entities should provide clear and convincing evidence of net benefit with the tests and treatments they offer. Given the controversy over the values and ethics of DTC screening companies and the services they offer, hospitals should clearly and publicly explain their relationships with DTC screening companies, given the lack of evidence to support mass vascular screenings. Hospitals also should justify such relationships transparently or, as Public Citizen suggests, sever such relationships.

---

[9] Snyder L, American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians ethics manual. Sixth edition. *Ann Intern Med*. 2012;156(1):73-104.
[10] Wallace EA, Schumann JH, Weinberger SE. Ethics of commercial screening tests. *Ann Intern Med*. 2012;157(10):747-748.
[11] Snyder L, American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians ethics manual: Sixth edition. *Ann Intern Med*. 2012;156(1):73-104.
[12] Public Citizen. Letters to twenty hospitals and medical institutions asking them to end their partnerships with HealthFair. http://www.citizen.org/hrg2206. Accessed October 2, 2014.
[13] Wallace EA, Schumann JH, Weinberger SE. Hospital relationships with direct-to-consumer screening companies. *JAMA*. 2014;312(9):891-892. Published online August 11, 2014. doi:10.1001/jama.2014.9500.

Finally, we would also like to call to your attention the fact that on January 22, 2015, Public Citizen requested that the Federal Trade Commission investigate the advertising and promotional activities of Life Line Screening. There is evidence that the company's advertising and promotional materials contain numerous statements that may be deceptive within the meaning of the Federal Trade Commission Act. These materials make unsubstantiated medical-benefit efficacy claims about Life Line Screening's primary cardiovascular disease and osteoporosis screening package, and they omit information material to consumers regarding the risks of adverse health-related outcomes and financial harms that may result from the screening.

Thank you for your prompt attention to this important patient safety and public health issue. Please contact us when HackensackUMC at Pascack Valley and Palisades Medical Center end their relationships with Life Line Screening.

Sincerely,

Vikram Krishnasamy, M.D., M.P.H.
Researcher
Public Citizen's Health Research Group

Michael Carome, M.D.
Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group

cc: Mark Sparta, Acting CEO, HackensackUMC at Pascack Valley
Bruce J. Markowitz, President and CEO, Palisades Medical Center

Appendix

Assessment of Cardiovascular Disease and Osteoporosis Screening Tests Offered by Life Line Screening

Life Line Screening heavily promotes directly to consumers a package of four cardiovascular disease screening tests plus an osteoporosis risk assessment test.[14,15] The four cardiovascular disease screening tests in the package are an electrocardiogram to screen for atrial fibrillation, a carotid artery ultrasound, an abdominal aortic aneurysm ultrasound, and a peripheral arterial disease test. The osteoporosis risk assessment test is an ultrasound of the heel bone to measure bone mass density.

Promotional materials describing these screening tests on the Life Line Screening website and in direct-to-consumer print solicitations mailed directly to people's homes misleadingly note the following:

> Since our inception in 1993, we have screened nearly eight million people, and currently screen nearly one million people each year at over 16,000 screening events nationwide. Through this experience, we often identify serious health issues and **have helped save thousands of lives**.[16] [Emphasis added]

> "These screenings have **proven to be safe and accurate** in detecting your risks of stroke and vascular disease – so you and your doctor can do something about it before it's too late."[17] [Emphasis added]

The Life Line Screening promotional materials recommend that adults over age 50 undergo these five screening tests annually:[18,19,20,21,22]

> Q. Who needs to be screened?
> A. The answer is anyone over 50 who wants to be proactive about his or her health. …

[14] Life Line Screening. Screening packages. http://www.lifelinescreening.com/What-We-Do/Screening-Packages. AccessedJanuary 9, 2015.
[15] Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
[16] Life Line Screening. Who we are. http://www.lifelinescreening.com/Who-We-Are. Accessed January 9, 2015.
[17] Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
[18] Life Line Screening. Atrial fibrillation screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Atrial-Fibrillation. Accessed January 9, 2015.
[19] Life Line Screening. Carotid artery disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Carotid-Artery-Disease. Accessed January 9, 2015.
[20] Life Line Screening. Abdominal aortic aneurysm screening.. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Abdominal-Aortic-Aneurysms. Accessed January 9, 2015.
[21] Life Line Screening. Peripheral arterial disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Peripheral-Arterial-Disease. Accessed January 9, 2015.
[22] Life Line Screening. Osteoporosis screening/bone density test. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Osteoporosis. Accessed January 9, 2015.

> However if you have a family history of stroke or heart disease, or if you have high risk factors such as being overweight, high cholesterol, smoking, or lack exercise you may wish to be screened, even if you are in your 40's.[23]

Life Line Screening's primary package is offered at a price of $149, purportedly providing consumers a "savings of $181."[24]

Life Line Screening seeks to prompt asymptomatic individuals for whom screening for asymptomatic cardiovascular disease and osteoporosis is *not clinically indicated* to undergo screening by using inappropriate direct-to-consumer advertisements and solicitations that target consumer fear about having undetected, potentially life-threatening diseases.[25] Examples of such statements found on Life Line Screening's website and print solicitation materials include the following:

- Website: "The absence of risk factors does **not** guarantee that a person will not die from a heart attack. In fact, 1 in 3 people who develop a myocardial infarction (MI) will not have any of the conventional risk factors, which include smoking, unhealthy diet, obesity, physical inactivity, high blood pressure, diabetes and raised lipids."[26] [Emphasis in original]

- Website: "Similarly, **80% – 85% of strokes occur without warning in asymptomatic patients**, so they can only be significantly reduced by finding and treating the disease before it happens."[27] [Emphasis added]

- Website: "Abdominal aortic aneurysms pose a threat because **they are usually silent until a medical emergency occurs**."[28] [Emphasis added]

- Website: "**Aneurysms are a health risk because they can burst or rupture. A ruptured aneurysm can cause severe internal bleeding, which can lead to shock or even death**."[29] [Emphasis in original]

- Website: "Your carotid arteries are the two large blood vessels in your neck that supply blood to your brain. When these arteries become clogged with cholesterol, they become

[23] Life Line Screening. Questions & answers about Life Line Screening. Enclosure to undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
[24] Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
[25] Lovett KM, Liang BA. Direct-to-consumer cardiac screening and suspect risk evaluation. *JAMA*. 2011;305(24):2567-2568.
[26] Life Line Screening. The benefits of ultrasound screening in key cardiovascular disease areas. http://www.lifelinescreeningresearch.com/the-benefits-of-ultrasound-screening/. Accessed January 9, 2015.
[27] *Ibid*.
[28] Life Line Screening. Abdominal aortic aneurysm screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Abdominal-Aortic-Aneurysms. Accessed January 9, 2015.
[29] Life Line Screening. Abdominal aortic aneurysm (AAA). http://www.lifelinescreening.com/~/media/Files/US/pdfs/FactSheetAAAupdated.ashx. Accessed January 9, 2015.

dangerously narrow. **If a blood clot occurs in the carotid arteries, then blood cannot reach your brain and a stroke can result**. "[30] [Emphasis added]

- Website: "A ruptured aortic aneurysm can cause massive internal bleeding and requires prompt emergency treatment to prevent death. **It is estimated that 80% of people with a ruptured aneurysm will die, and that many of these will die before being able to reach a hospital.**"[31] [Emphasis added]

- Website: "As we age, bones begin to break down faster than new bone can be formed. Osteoporosis removes minerals from bones until they become so weak and brittle that they fracture very easily. Actions such as bending to pick up a newspaper, lifting a vacuum, or even coughing can cause a fracture. **Some fractures, such as hip fractures, may require hospitalization or major surgery, and may result in disability or even death**."[32] [Emphasis added]

- Direct-to-consumer letter: "These screenings have proven to be safe and accurate in detecting **your risks of stroke and vascular disease** – so you and your doctor **can do something about it before it's too late**."[33] [Emphasis added]

- Direct-to-consumer letter: "The lifetime risk of stroke for middle-aged men and women is 1 in 5 for women and 1 in 6 for men, and **it takes a terrible toll on families**."[34] [Emphasis added]

- Direct-to-consumer letter: "Life Line Screening has conducted nearly 8 million screenings, and customers sometimes tell us they feel the **screenings saved their lives**."[35] [Emphasis added]

- Direct-to-consumer letter:[36] "What's inside <u>your</u> arteries?" [Emphasis in original]

As discussed below, a review of current evidence-based guidelines and relevant scientific literature fails to provide support for use of these five tests — individually or together as a package — for widespread screening of asymptomatic individuals in the general adult population over age 50 on a one-time basis, let alone annually. For many individuals, the risks of harm outweigh the benefits of the testing. Moreover, since the tests are not clinically indicated for most people being screened, and since many people will undergo additional unnecessary testing, these screenings are resulting in financial harm to many individuals.

---

[30] Life Line Screening. Carotid artery disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Carotid-Artery-Disease. Accessed January 9, 2015.
[31] *Ibid*.
[32] Life Line Screening. Osteoporosis screening/bone density test. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Osteoporosis. Accessed January 9, 2015.
[33] Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
[34] *Ibid*.
[35] *Ibid*.
[36] *Ibid*.

Although the following screening tests sound appealing, each one either: (a) clinically benefits only appropriately selected high-risk groups of patients (rather than *all* adults over age 50); or (b) has not been scientifically proven to provide any clinically meaningful benefit to anyone. Widespread and indiscriminate use of these tests is likely to be harmful to large numbers of individuals in the general, asymptomatic population by yielding a significant number of false-positive test results, leading to subsequent unnecessary diagnostic procedures and treatments, associated adverse effects of those procedures and treatments, and unwarranted anxiety in tested individuals. In addition, some individuals undergoing inappropriate screening will have true-positive abnormal results, but the abnormalities found will never cause symptoms or death, leading to overdiagnosis.

A. Atrial fibrillation screening with electrocardiogram (ECG):

The Life Line Screening online promotional materials state:[37]

> Atrial Fibrillation is the most common type of heart arrhythmia (abnormal heartbeat). It occurs when the heart's upper chambers (the atria) beat irregularly or quiver. Without an effective heartbeat blood isn't pumped completely out of the atria, causing blood to pool and possibly clot. A clot can travel to other parts of the body, including the brain, where it may result in stroke.
>
> Screening for Atrial Fibrillation
>
> - A non-invasive procedure used to detect irregular heartbeat (a major risk factor for stroke), an Atrial Fibrillation screening is performed by attaching [ECG] electrodes above your wrists and ankles.
>
> Who should have an atrial fibrillation screening?
>
> - Anyone with risk factors for stroke, atrial fibrillation or carotid artery disease
>
> How often should I get an atrial fibrillation screening?
>
> - Annually

However, we are not aware of any major medical professional organization that endorses widespread screening of asymptomatic patients younger than age 65 for atrial fibrillation. In addition, atrial fibrillation can be detected in most patients who have the condition simply by checking for an irregularly irregular pulse during a physical exam.

In 2011, the American Heart Association (AHA) and the American Stroke Association (ASA) jointly issued updated evidence-based guidelines for the primary prevention of stroke.[38] The

[37] Life Line Screening. Atrial fibrillation screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Atrial-Fibrillation. Accessed January 9, 2015.

American Academy of Neurology (AAN) affirmed the value of these guidelines. The 2011 AHA/ASA guidelines provided the following recommendation regarding screening for atrial fibrillation:

> Active screening for atrial fibrillation in patients >65 years of age in primary care settings using pulse taking followed by an ECG as indicated can be useful.

In 2014, the AHA and the ASA issued updated evidence-based guidelines for the primary prevention of stroke.[39] The AAN again affirmed the value of the updated guidelines, and the American Association of Neurological Surgeons, the Congress of Neurological Surgeons and the Preventive Cardiovascular Nurses Association endorsed them. The update provided the following recommendation regarding screening for atrial fibrillation:

> Active screening for AF in the primary care setting in patients >65 years of age by pulse assessment followed by ECG as indicated can be useful.

In 2010 and 2012, the European Society of Cardiology issued evidence-based guidelines that similarly recommended that patients ages 65 and older be screened for atrial fibrillation by their primary health care providers by checking the pulse, followed by an ECG in case of irregularity.[40,41]

B. Stroke/Carotid Artery Ultrasound:

The Life Line Screening online promotional materials state:[42]

> Your carotid arteries are the two large blood vessels in your neck that supply blood to your brain. When these arteries become clogged with cholesterol, they become dangerously narrow. If a blood clot occurs in the carotid arteries, then blood cannot reach your brain and a stroke can result. …

---

[38] Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the primary prevention of stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42(2):517-584. [see page 1 for title, authors, ANA affirmation; see page 21 for recommendation]

[39] Meschia JF, Bushnell C, Goden-Albala B, et al. Guidelines for the primary prevention of stroke: A statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45(12):3754-3832. [see page 1 for title, authors, ANA affirmation and other endorsements; see page 24 for recommendation]

[40] Camm AJ, Kirchhof P, Lip GYH, et al. Guidelines for the management of atrial fibrillation: The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). *Eur Heart J*. 2010;31:2369-2429. [See page 50]

[41] Camm AJ, Lip GYH, De Caterina R, et al. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: An update of the 2010 ESC Guidelines for the management of atrial fibrillation. *Eur Heart J*. 2012;33(21):2719-2747. [See page 2723]

[42] Life Line Screening. Carotid artery disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Carotid-Artery-Disease. Accessed January 9, 2015.

Carotid Artery Disease (Plaque) Screening

- Simple, painless and non-invasive, this screening uses cutting-edge Doppler color flow ultrasound technology to create images of the carotid arteries while also measuring blood flow through them.

Who should have a carotid artery screening?

- Anyone over age 50
- Anyone over age 40 with risk factors

How often should I get a carotid artery screening?

- Annually

However, several major medical professional organizations affirmatively recommend *against* indiscriminate screening with carotid artery ultrasounds in low-risk, asymptomatic individuals, and we are not aware of any major medical professional organization that endorses such screening.

Good evidence indicates that although stroke is a leading cause of death and disability in the United States, a relatively small proportion of all disabling, unheralded strokes are due to carotid artery disease. Studies also suggest that only about 1 percent of the general population older than 65 has severe carotid artery stenosis (60 to 90 percent narrowing).[43] Carotid artery stenosis is more prevalent in older adults, smokers, those with hypertension and those with heart disease; unfortunately, research has not found any single risk factor or clinically useful risk stratification tool that can reliably and accurately distinguish people who have clinically important carotid artery stenosis from those who do not.[44]

In 2006, the AHA and the ASA issued a series of evidence-based guidelines for the primary prevention of stroke.[45] The value of the guidelines was affirmed by the AAN. Although the guidelines did not include a specific recommendation about screening the general population for asymptomatic carotid stenosis, they did state the following:

> Although highly selected patients may benefit, screening of general populations for asymptomatic carotid stenosis is unlikely to be cost-effective. The cost-effectiveness of even a one-time screening approach would be highly dependent on the ability to identify a group of persons with a high pretest likelihood of having high-grade asymptomatic disease, the availability of a screening test with a very high sensitivity and specificity when used on a side-scale basis, and very low perioperative complication rates.

[43] U.S. Preventive Services Task Force. Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2007;147(12):854-859.
[44] *Ibid*.
[45] Goldstein LB, Adams R, Alberts MJ, et al. Primary prevention of ischemic stroke: A guideline from the American Heart Association/American Stroke Association Stroke Council. *Stroke*. 2006;37(6):1583-633.

These conditions for cost-effective screening are not met for carotid artery ultrasound screening of asymptomatic individuals in the general population, as discussed below.

In 2011, the AHA and the ASA issued updated guidelines for the primary prevention of stroke, the value of which was again affirmed by the AAN.[46] The updated guidelines stated the following:

> Population screening for asymptomatic carotid artery stenosis is not recommended.

In 2014, the AHA and the ASA issued updated guidelines for the primary prevention of stroke.[47] The AAN again affirmed the value of the updated guidelines, and the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and the Preventive Cardiovascular Nurses Association endorsed them. The updated guidelines stated the following:

> Screening low-risk populations for asymptomatic carotid artery stenosis is not recommended.

In 2007, the U.S. Preventive Services Task Force (USPSTF) issued an evidence-based grade D recommendation *against* screening for asymptomatic carotid artery stenosis in the general population.[48] In making this a grade D recommendation, the USPSTF concluded with moderate certainty that for individuals with asymptomatic carotid artery stenosis, the benefits of screening do not outweigh the harms. It noted, in particular, the following:

> **Importance**
>
> Good evidence indicates that although stroke is a leading cause of death and disability in the United States, a relatively small proportion of all disabling, unheralded strokes is due to [carotid artery stenosis].
>
> **Detection**
>
> The most feasible screening test for severe [carotid artery stenosis] (for example, 60% to 99% stenosis) is duplex ultrasonography. Good evidence indicates that this test has moderate sensitivity and specificity and yields many false-positive results. A positive result on duplex ultrasonography is often confirmed by digital subtraction angiography, which is more accurate but can cause serious adverse events. Noninvasive confirmatory tests, such as magnetic resonance angiography, involve some inaccuracy. Given these facts, some people with false-positive test results may receive unnecessary invasive carotid endarterectomy surgery.

[46] Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the primary prevention of stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42(2):517-584. [see page 1 for title, authors, ANA affirmation; see page 25 for recommendation]

[47] Meschia JF, Bushnell C, Goden-Albala B, et al. Guidelines for the primary prevention of stroke: A statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45(12):3754-3832. [see page 1 for title, authors, ANA affirmation and other endorsements; see page 30 for recommendation]

[48] U.S. Preventive Services Task Force. Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2007;147(12):854-9.

Benefits of Detection and Early Intervention

Good evidence indicates that in selected, high-risk trial participants with asymptomatic severe [carotid artery stenosis], carotid endarterectomy by selected surgeons reduces the 5-year absolute incidence of all strokes or perioperative death by approximately 5%. These benefits would be less among asymptomatic people in the general population. For the general primary care population, the benefits are judged to be no greater than small.

Harms of Detection and Early Intervention

Good evidence indicates that both the testing strategy and the treatment with carotid endarterectomy can cause harms. A testing strategy that includes angiography will itself cause some strokes. A testing strategy that does not include angiography will cause some strokes by leading to carotid endarterectomy in people who do not have severe [carotid artery stenosis]. In excellent centers, carotid endarterectomy is associated with a 30-day stroke or mortality rate of about 3%; some areas have higher rates. These harms are judged to be no less than small.

In July 2014, the USPSTF issued an updated recommendation against screening for asymptomatic carotid artery stenosis in the general population.[49] In reaffirming its prior recommendation, the USPSTF concluded with moderate certainty that the harms of screening for asymptomatic carotid artery stenosis outweigh the benefits. The USPSTF presented the following updated rationale:[50]

Importance

Stroke is a leading cause of death and disability in the United States. Although asymptomatic carotid artery stenosis is a risk factor for stroke, it causes a relatively small proportion of strokes.

Detection

The most feasible screening test for carotid artery stenosis (defined as 60% to 99% stenosis) is ultrasonography. Although adequate evidence indicates that this test has high sensitivity and specificity, in practice, ultrasonography yields many false-positive results in the general population, which has a low prevalence of carotid artery stenosis (approximately 0.5% to 1%). There are no externally validated, reliable tools that can determine who is at increased risk for carotid artery stenosis or for stroke when carotid artery stenosis is present. Adequate evidence indicates that the accuracy of screening by auscultation of the neck is poor.

Benefits of Detection and Early Intervention

There is no direct evidence on the benefits of screening for carotid artery stenosis. Adequate evidence indicates that in selected trial participants with asymptomatic carotid artery stenosis, carotid endarterectomy (CEA) performed by selected surgeons reduces the absolute incidence of all strokes or perioperative death by approximately 3.5%

[49] LeFevre on behalf of the U.S. Preventive Services Task Force. Screening for asymptomatic carotid artery stenosis: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. Published online July 8, 2014. doi:10.7326/M14-1333.

[50] *Ibid*.

compared with (outdated) medical management. However, this difference is probably smaller with current optimal medical management. The magnitude of these benefits would be smaller in asymptomatic persons in the general population. For the general primary care population, the magnitude of benefit is small to none. There is no evidence that identification of asymptomatic carotid artery stenosis leads to any benefit from adding or increasing medication doses (beyond current standard medical therapy for cardiovascular disease prevention).

Harms of Detection and Early Intervention
Adequate evidence indicates that both the testing strategy for carotid artery stenosis and treatment with CEA can cause harms. Although screening with ultrasonography has few direct harms, all screening strategies, including those with or without confirmatory tests (that is, digital subtraction or magnetic resonance angiography), have imperfect sensitivity and specificity and could lead to unnecessary interventions and result in serious harms. In selected centers similar to those in the trials, CEA is associated with a 30-day stroke or mortality rate of approximately 2.4%; reported rates are as high as approximately 5% in low-volume centers and 6% in certain states. Myocardial infarctions are reported in 0.8% to 2.2% of patients after CEA. The 30-day stroke or mortality rate after carotid angioplasty and stenting (CAAS) is approximately 3.1% to 3.8%. The overall magnitude of harms of screening and subsequent treatment of asymptomatic carotid artery stenosis is small to moderate depending on patient population, surgeon, center volume, and geographic location.

In 2007, the American Society of Neuroimaging, with co-sponsorship by the Society of Vascular and Interventional Neurology, issued evidence-based recommendations on the screening of asymptomatic carotid artery disease in the general population and selected subsets of patients.[51] These societies issued a grade E recommendation *against* screening for carotid artery stenosis in the general population or in a selected population based on age, gender or any other variable alone. The criteria for a grade E recommendation were that the prevalence of disease may be high or low but detection and treatment is documented to have no benefit, or prevalence of disease is low. They also issued a grade A recommendation that screening of selective subpopulations of adults age 65 or older with at least three cardiovascular risk factors (hypertension, coronary artery disease, current cigarette smoking or hyperlipidemia) needs to be considered. The criteria of a grade A recommendation were that the prevalence of disease is high and detection and treatment is of documented benefit.

In 2011, the Society for Vascular Surgery issued a position statement recommending ultrasound screening of carotid arteries only for high-risk individuals age 55 or older, taking into account cardiovascular risk factors, such as a history of hypertension, diabetes mellitus, smoking,

[51] Qureshi AI, Alexandrov AV, Tegeler CH, et al. Guidelines for screening of extracranial carotid artery disease: a statement for healthcare professionals from the multidisciplinary practice guidelines committee of the American Society of Neuroimaging; cosponsored by the Society of Vascular and Interventional Neurology. *J Neuroimaging*. 2007;17(1):19-47.

hypercholesterolemia, or known cardiovascular disease.[52] The position statement provided little substantive evidence to support this recommendation.

Thus, screening for carotid artery stenosis with ultrasound in the general, asymptomatic population has *not* been shown to significantly improve clinical outcomes, and numerous medical professional organizations strongly recommend against such screening.

C. Abdominal Aortic Aneurysm Ultrasound:

The Life Line Screening online promotional materials state:[53]

> An Abdominal Aortic Aneurysm (AAA), a specific kind of aneurysm, is a condition in which the lining of the blood vessel called the aorta is enlarged within the abdomen. Abdominal aortic aneurysms pose a threat because they are usually silent until a medical emergency occurs.
>
> The abdominal aorta is the largest blood vessel in the body and the main artery that originates in the heart. As the lining weakens from age and other risk factors, the vessel wall thins and expands. …
>
> Screening for Aortic Aneurysms
>
> - A painless, non-invasive procedure, an abdominal aortic aneurysm screening requires you to lie on your back while a technician uses ultrasound to take images and measurements of your abdominal aorta. …
>
> Who should have an aortic aneurysm screening?
>
> - Anyone with risk factors
>
> How often should I get an aortic aneurysm screening?
>
> - Annually

By definition, an AAA is present when aortic diameter equals or exceeds 3.0 cm (slightly more than one inch).[54] Most people who have an AAA show no signs or symptoms until it ruptures. The strongest risk factor for *rupture* of an AAA is the aortic diameter.[55] Thus, risk of AAA rupture rises with increasing size of the aneurysm. AAAs with a diameter between 3.0 and 3.9

[52] Society for Vascular Surgery. SVS position statement on vascular screenings. January 2011. http://www.vascularweb.org/about/positionstatements/Pages/svs-position-statement-on-vascular-screening.aspx. AccessedJanuary 14, 2015.
[53] Life Line Screening. Abdominal aortic aneurysm screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Abdominal-Aortic-Aneurysms. AccessedJanuary 9, 2015.
[54] Fleming C, Whitlock EP, Beil TL, Lederle FA. Screening for abdominal aortic aneurysm: A best-evidence systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2005;142(3):203-211.
[55] Lederle FA, Johnson GR, Wilson SE, et al. Rupture rate of large abdominal aortic aneurysms in patients refusing or unfit for elective repair. *JAMA*. 2002;287(22):2968-2972.

cm have an essentially 0 percent annual rupture risk; those with between 4.0 and 4.9 cm have a 1 percent risk; and those between 5.0 and 5.9 cm have a 11 percent annual rupture risk.[56]

In a study of an unselected general population in the U.K., the prevalence of AAA was six times greater in men than women for all age groups.[57] For men not screened for AAA, almost all deaths from ruptured AAAs occurred after age 65, with more than half occurring before age 80.[58] For women not screened for AAA, the majority of AAA-related deaths occurred after age 80.[59]

Several major medical professional organizations affirmatively recommend one-time ultrasound screening for AAAs *only in certain high-risk individuals* given the epidemiology of AAAs described above, and we are not aware of any major medical professional organization that endorses indiscriminate ultrasound screening for AAAs in low-risk, asymptomatic individuals.

In 2005, the USPSTF issued the following evidence-based recommendations for AAA screening:[60]

(1) A grade B recommendation for one-time screening for AAA by ultrasonography in men age 65 to 75 who have ever smoked. In making this a grade B recommendation, the USPSTF offered the following rationale:

> The USPSTF found good evidence that screening for AAA and surgical repair of large AAAs (≥5.5 cm) in men age 65 to 75 years who have ever smoked (current and former smokers) leads to decreased AAA-specific mortality. There is good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance (that is, in an accredited facility with credentialed technologists), is an accurate screening test for AAA. There is also good evidence of important harms of screening and early treatment, including an increased number of surgeries with associated clinically significant morbidity and mortality, and short-term psychological harms. On the basis of the moderate magnitude of net benefit, the USPSTF concluded that the benefits of screening for AAA in men age 65 to 75 years who have ever smoked outweigh the harms.

(2) No recommendation for or against screening for AAA in men age 65 to 75 who have *never* smoked. In making this grade C recommendation, the USPSTF offered the following rationale:

> The USPSTF found good evidence that screening for AAA in men age 65 to 75 years who have never smoked leads to decreased AAA-specific mortality. There is, however, a lower prevalence of large AAAs in men who have never smoked

[56] LeFevre ML on behalf of the U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. Online June 24, 2014. doi: 10.7326/M14-1204.
[57] Scott RA, Bridgewater SG, Ashton HA. Randomized clinical trial of screening for abdominal aortic aneurysm in women. *Br J Surg.* 2002;89(3):283-285.
[58] *Ibid*.
[59] *Ibid*.
[60] U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: Recommendation statement. *Ann Intern Med*. 2005;142(3):198-202.

> compared with men who have ever smoked; thus, the potential benefit from screening men who have never smoked is small. There is good evidence that screening and early treatment lead to important harms, including an increased number of surgeries with associated clinically significant morbidity and mortality, and short-term psychological harms. The USPSTF concluded that the balance between the benefits and harms of screening for AAA is too close to make a general recommendation in this population.

(3) A grade D recommendation *against* routine screening for AAA in women. In making this a grade D recommendation, the USPSTF offered the following rationale:

> Because of the low prevalence of large AAAs in women, the number of AAA-related deaths that can be prevented by screening this population is small. There is good evidence that screening and early treatment result in important harms, including an increased number of surgeries with associated morbidity and mortality, and psychological harms. The USPSTF concluded that the harms of screening women for AAA therefore outweigh the benefits.

In June 2014, the USPSTF issued a revised recommendation statement, based on an updated review of the available evidence published between January 2004 and January 2013.[61] The updated recommendations differ slightly from the 2005 recommendations and include the following:[62]

(1) A grade B recommendation for one-time screening for AAA with ultrasonography in men ages 65 to 75 who have ever smoked (no change from 2005). The USPSTF provided the following updated rationale for this unchanged recommendation:

> Four large, population-based, randomized, controlled trials (RCTs) show that invitation to 1-time screening for AAA is associated with reduced AAA-specific mortality in men. This benefit begins 3 years after testing and persists up to 15 years. In addition, risk reduction for AAA rupture and emergency surgery persists up to 10 to 13 years.
>
> In the 2 highest-quality trials, the relative reduction in AAA-specific mortality after 13 years was 42% to 66%. In the largest trial, where prevalence of AAA was approximately 5% in the screened group, screening was associated with an absolute risk reduction in death of 1.4 per 1000 men.
>
> Abdominal aortic aneurysms are most prevalent in men who have ever smoked, occurring in approximately 6% to 7% of this population. This prevalence increases the importance of screening in these men because it maximizes the absolute benefit that could be achieved (that is, it improves the likelihood that

[61] Guirguis-Blake JM, Beil TL, Senger CA Whitlock EP. Ultrasonography screening for abdominal aortic aneurysms: A systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2014;160(5):321-329.

[62] LeFevre ML on behalf of the U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;161(4):281-290..

> men in this group will benefit from screening). Convincing evidence shows that 1-time screening with ultrasonography results in a moderate benefit in men aged 65 to 75 years who have ever smoked.

The USPSTF concluded with high certainty that screening for AAA with ultrasonography in men ages 65 to 75 who have ever smoked has a moderate net benefit.

(2) A grade C recommendation that clinicians *selectively* offer screening for AAA in men ages 65 to 75 who have never smoked rather than routinely screening all men in this group. Evidence indicates that the net benefit of screening all men ages 65 to 75 years who have never smoked is small. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the balance of benefits and harms on the basis of evidence relevant to the patient's medical history, family history, other risk factors, and personal values. The USPSTF offered the following rationale for this new recommendation:

> Screening men overall reduces AAA-specific death, rupture, and emergency surgery. However, the lower prevalence of AAA in men who have never smoked (approximately 2%) substantially reduces the absolute benefit (that is, it greatly lowers the probability that men in this group will benefit from screening). Adequate evidence shows that 1-time screening for AAA with ultrasonography results in a small benefit in men aged 65 to 75 years who have never smoked.

The USPSTF also suggested the following clinical considerations with respect to this new recommendation:

> Despite the demonstrated benefits of screening for AAA in men overall, the lower prevalence of AAA in male never-smokers versus male ever-smokers suggests that clinicians should consider a patient's risk factors and the potential for harm before screening for AAA rather than routinely offering screening to all male never-smokers. Important risk factors for AAA include older age and a first-degree relative with an AAA; other risk factors include a history of other vascular aneurysms, coronary artery disease, cerebrovascular disease, atherosclerosis, hypercholesterolemia, obesity, and hypertension. Factors associated with a reduced risk for AAA include African American race, Hispanic ethnicity, and diabetes.

(3) An I statement concluding that the current evidence is insufficient to assess the balance of benefits and harms of screening for AAA in women ages 65 to 75 who have ever smoked. (An I statement means the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence may be lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.) The USPSTF offered the following rationale for this draft statement:

> *Potential Preventable Burden.* A screening study in Sweden found that the prevalence of AAA in women aged 70 years was low (0.8%) for ever-smokers but increased to 2.0% for current smokers. A meta-analysis of individual-patient data

found that women have a higher risk than men for AAA rupture at the same diameter (hazard ratio [HR], 3.76 [95% CI, 2.58 to 5.47]). However, AAA-associated deaths occur at an older age in women (at a time of increased competing causes of death and a declining benefit–risk ratio for operative interventions), with 70% of deaths occurring after age 80 years in women compared with fewer than 50% in men. In the only screening RCT that included women, most screen-detected AAAs in women were small (3.0 to 3.9 cm) and AAA-specific mortality was low in screened and unscreened women (<0.2%) after 10 years.

Potential Harms. Four RCTs (primarily done in men) showed that screening for AAA doubled the rate of AAA-associated surgeries, largely driven by an increase in elective surgeries. Most screen-detected AAAs were below the 5.5-cm threshold for immediate repair. This finding generally results in long-term or lifelong surveillance and is probably associated with some amount of overtreatment, although the magnitude of this burden is difficult to quantify.

Most screening trials reported an associated decrease in emergency AAA repairs and a reduced 30-day mortality rate associated with emergency surgery in populations invited to screen, although mortality associated with elective surgery was not reduced. Operative mortality associated with AAAs is higher in women than in men (7% vs. 5% for open repair and 2% vs. 1% for endovascular repair, respectively).

Costs. In addition to the cost of ultrasonography screening (approximately $100), the estimated potential associated cost of elective surgery to repair a screen-detected AAA ranges from $37 000 to $43 000. Potential opportunity costs also may arise, because screening may take the place of other preventive activities that may be more beneficial to the patient.

Current Practice. Screening for AAA is provided as part of the “welcome-to-Medicare visit” for women who have a family history of AAA. However, the evidence is insufficient to accurately characterize current practice patterns related to screening for AAA in women.

A retrospective analysis from 2000 to 2010 used the National Inpatient Sample, a database that has a stratified 20% random sample of all nonfederal inpatient hospital admissions in the United States. This analysis found that women are more likely than men to have open surgery versus endovascular aneurysm repair (EVAR) for unruptured AAA (24% vs. 17%, respectively), potentially because of issues with access to the iliac artery (that is, smaller artery size) that may preclude endovascular management.

A retrospective review of 4026 AAA repairs in the Vascular Study Group of New England database (a voluntary registry from 30 academic and community hospitals in the 6 New England states) reported that women were more likely than men to have open surgery versus EVAR and to be older and have smaller aortic

> diameters at the time of repair. Postoperative complications were higher in women than in men after elective EVAR or open repair, including emergency reoperations, dysrhythmias, leg ischemia or emboli, bowel ischemia, or need for discharge to another medical facility rather than home.

(4) A grade D recommendation *against* routine screening for AAA in women who have never smoked. The USPSTF offered the following rationale for this draft updated recommendation:

> The prevalence of AAA in women who have never smoked is low (0.03% to 0.60% in women aged 50 to 79 years). The evidence also shows no apparent benefit of screening for AAA in women. The USPSTF therefore concludes that adequate evidence shows that the absolute benefit of 1-time screening for AAA with ultrasonography in women who have never smoked can effectively be bounded at none or almost none.

In discussing the harms of detection and early treatment of AAAs, the USPSTF noted the following:[63]

> In the available trials, groups invited to screening were approximately twice as likely as control groups to have any AAA surgery within 3 to 5 years, predominantly driven by an increase in elective surgeries. More than 90% of AAAs identified by screening were below the 5.5-cm threshold for immediate repair. Detecting smaller AAAs generally leads to long-term (potentially lifelong) surveillance.
>
> A person's risk for death related to elective surgery for AAA is lower than that for death related to emergency surgery for rupture. However, the increase in the overall rates of detection and surgery in the screening groups still potentially represents a harm. A proportion of AAAs will never rupture because they do not advance or because a person dies of a competing cause.
>
> The exact extent of overdiagnosis and overtreatment is difficult to estimate. One study from Massachusetts General Hospital reviewed 24 000 consecutive autopsies between 1952 and 1975 and found that 75% of the 473 patients who died with an undetected or unoperated AAA had a cause of death not related to the AAA (41% were >5.1 cm in diameter). Given that even elective treatment is associated with some risk for perioperative mortality, overtreatment is an important issue to consider when deciding whether to screen for this condition. …
>
> Convincing evidence shows that the harms associated with 1-time screening for AAA with ultrasonography are at least small in all populations and potentially higher in women because of their higher risk for operative mortality.

In 2011, the Society for Vascular Surgery issued a position statement on vascular screening recommending a one-time ultrasound screening for AAA for all men age 65 or older and

[63] *Ibid.*

screening men as early as age 55 who have a family history of AAA.[64] The society also recommended one-time ultrasound screening for AAA for all women age 65 or older who have a family history of AAA or have smoked.

In 2012, the ACCF, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery jointly issued evidence-based appropriate use criteria for noninvasive vascular testing (ultrasound and physiological testing) for a variety of possible indications.[65] For each indication, these organizations classified the use of noninvasive vascular testing into one of the following three categories:

- **Appropriate:** The test is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences — including the risks of the procedure itself and the downstream impact of poor test performance such as delay in diagnosis (false-negatives) or inappropriate diagnosis (false-positives) — by a sufficiently wide margin for the specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.

- **Uncertain:** The test *may* be generally acceptable and *may* be a reasonable approach for the specific indication; uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.

- **Inappropriate:** The test *is not* generally acceptable and *is not* a reasonable approach for the specific indication.

These organizations classify screening for AAA as *inappropriate* for anyone under age 65 with no history of smoking, except as noted below. They also classify such screening as *uncertain* for anyone 65 or older with no history of smoking.

These organizations did classify screening for AAA as *appropriate* for the following subgroups:

- Adults older than age 60 with a first-degree relative with an AAA.
- Adults age 65 or older who are current or former smokers.

In summary, the USPSTF and many other major medical professional organizations recommended against routine screening for AAA, or designate such screening as inappropriate for those individuals who are not at high risk for developing AAA. Screening for AAA in the

[64] Society for Vascular Surgery. SVS Position Statement on Vascular Screenings. January 2011. http://www.vascularweb.org/about/positionstatements/Pages/svs-position-statement-on-vascular-screening.aspx. Accessed August 21, 2014.

[65] Mohler ER, Gornik HL, Gerhard-Herman M, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/ SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. *J Am Coll Cardiol*. 2012;60(3):242-276.

general, asymptomatic population has *not* been shown to significantly improve clinical outcome and is likely to do more harm than good.

D. Peripheral Arterial Disease Test:

The Life Line Screening online promotional materials state:[66]

> Peripheral Arterial Disease (PAD), more commonly known as hardening of the arteries, affects about eight million Americans. It is a condition in which the large and medium-sized arteries supplying blood to the legs become narrow or clogged, constricting the flow of blood. PAD is caused by atherosclerosis, a gradual process in which cholesterol and scar tissue build up, forming a substance called plaque that clogs the artery. PAD not only causes pain and disability, it also is associated with a much higher risk of heart disease. …
>
> Peripheral Arterial Disease Screening
>
> - A quick, easy and non-invasive procedure, PAD screening is done by using the ankle-brachial index (ABI). After removing your socks and shoes, you will have pressure cuffs placed around your upper arms and ankles. A small ultrasound device will then measure the systolic blood pressure in your limbs. …
>
> Who should have a peripheral arterial disease screening?
>
> - Anyone with risk factors
>
> How often should I get a peripheral arterial disease screening?
>
> - Annually

In 2012, the ACCF, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery jointly issued evidence-based appropriate use criteria for noninvasive vascular testing (ultrasound and physiological testing) for a variety of possible indications. These appropriate use criteria identify the following as the only appropriate indications for lower extremity artery testing with ABI: patients with diminished pulses, femoral bruit, age greater than 50 with diabetes or smoking, or age greater than 70, which is consistent with ACC/AHA PAD guidelines. The evaluation with ABI for those younger than 50 and those with diabetes was classified as uncertain.[67]

---

[66] Life Line Screening. Peripheral arterial disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Peripheral-Arterial-Disease. Accessed January 9, 2015.

[67] Mohler ER, Gornik HL, Gerhard-Herman M, et al. ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 appropriate use criteria for peripheral vascular ultrasound and physiological testing part I: Arterial ultrasound and physiological testing. *J Am Coll Cardiol*. 2012;60(3):242-276.

In 2013, the USPSTF, based on a systematic review of the scientific literature,[68] issued a grade I statement on ABI testing, concluding that the current evidence is *insufficient* to assess the balance of benefits and harms of screening for peripheral artery disease and cardiovascular disease risk assessment with ABI in adults.[69] In making this statement, the USPSTF noted the following regarding its assessment of the possible benefits and harms of ABI screening:

> **Benefits of Detection and Early Treatment**
>
> The USPSTF found no evidence that screening for and treatment of PAD in asymptomatic patients leads to clinically important benefits. It also reviewed the potential benefits of adding the ABI to the Framingham Risk Score (FRS) and found evidence that this results in some patient risk reclassification; however, how often the reclassification is appropriate or whether it results in improved clinical outcomes is not known.
>
> Determining the overall benefit of ABI testing requires not only evidence on appropriate risk reclassification but also evidence that this reclassification leads to treatments shown to improve clinical outcomes. One randomized trial found that aspirin did not reduce [cardiovascular disease] events in patients with a low ABI. No studies assessed the effect of lipid-lowering therapy or other cardiovascular risk reduction interventions in patients with asymptomatic PAD and no known diagnosis of [cardiovascular disease] or diabetes. The USPSTF found inadequate evidence that early treatment of screen-detected PAD leads to improvement in clinical outcomes.
>
> **Harms of Detection and Early Treatment**
>
> The USPSTF found no studies addressing the magnitude of harms of screening for PAD with the ABI; however, the direct harms to the patient of screening itself, beyond the time needed for the test, are probably minimal. Other harms resulting from testing may include false-positive results, exposure to gadolinium or contrast dye if magnetic resonance angiography (MRA) or computed tomography angiography (CTA) is used to confirm diagnosis, anxiety, labeling, and opportunity costs.
>
> The USPSTF found inadequate evidence on the harms of early treatment of screen-detected PAD. One study showed that low-dose aspirin treatment in asymptomatic patients with a low ABI may increase bleeding. Additional harms associated with treatment include use of unnecessary medications (or higher doses) and their resulting adverse effects and discontinuation of medications known to be effective in patients with established coronary artery disease (CAD) if the patient is reclassified to a lower risk category on the basis of a normal ABI.

We are not aware of any major medical professional organization that endorses such screening for peripheral vascular disease with ABI in the general asymptomatic population.

Moreover, treatment benefits for asymptomatic individuals with screen-detected PAD are not well established, and there appear to be no studies that directly assess the impact of screening

[68] Lin JS, Olson CM, Johnson ES, Whitlock EP. The ankle-brachial index for peripheral artery disease screening and cardiovascular disease prediction among asymptomatic adults: A systematic evidence review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2013;159(5):333-341.

[69] Moyer VA, U.S. Preventive Services Task Force. Screening for peripheral artery disease and cardiovascular disease risk assessment with the ankle–brachial index in adults: U.S. Preventive Service Task Force recommendation statement. *Ann Intern Med.* 2013;159(5):342-348.

unselected adults (or generally asymptomatic adults) with ABI on cardiovascular disease or PAD health outcomes.[70]

E. Osteoporosis Screening/Bone Density Test

The Life Line Screening online promotional materials state:[71]

> Osteoporosis is a disease in which bone becomes extremely fragile. Bone is a complex living tissue that can be weakened by poor diet and lack of exercise.
>
> As we age, bones begin to break down faster than new bone can be formed. Osteoporosis removes minerals from bones until they become so weak and brittle that they fracture very easily. Actions such as bending to pick up a newspaper, lifting a vacuum, or even coughing can cause a fracture. Some fractures, such as hip fractures, may require hospitalization or major surgery, and may result in disability or even death.
>
> Screening for Osteoporosis
>
> - An easy and painless procedure, an osteoporosis screening requires you to place your foot in an ultrasound device called a bone densitometer. This device then measures the bone mineral density [BMD] of your heel. The heel is measured because its bone is similar to that found in the hip, where fractures most often occur. …
>
> Who should have an Osteoporosis screening?
>
> - Anyone who has the risk factors associated with the disease …
>
> How often should I get an Osteoporosis screening?
>
> - Annually

Several major medical professional organizations affirmatively recommend screening for osteoporosis in *certain high-risk individuals*, but we are not aware of any major medical professional organization that endorses such screening *annually* for any group of individuals.

In 2008, the American College of Physicians issued the following evidence-based recommendation for osteoporosis screening in men:[72]

> (1) Clinicians should periodically perform individualized assessment of risk factors for osteoporosis in older men (Grade: strong recommendation; moderate-quality evidence).

---

[70] Lin JS, Olson CM, Johnson ES, et al. *The Ankle Brachial Index for Peripheral Artery Disease Screening and Cardiovascular Disease Prediction in Asymptomatic Adults: A Systematic Evidence Review for the U.S. Preventive Services Task Force*. Rockville, MD: Agency for Healthcare Research and Quality; 2013. http://www.ncbi.nlm.nih.gov/books/NBK164524. Accessed December 29, 2014.

[71] Life Line Screening. Osteoporosis screening/bone density test. http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For/Osteoporosis. Accessed January 9, 2015.

[72] Qaseem A, Snow V, Shekelle P, et al. Screening for osteoporosis in men: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2008;148(9):680-4.

> A careful assessment of risk for osteoporosis in men is important. The appropriate age to start risk assessment is uncertain. However, by age 65 years, at least 6% of men have DXA [dual-energy X-ray absorptiometry]-determined osteoporosis, therefore, assessment of risk factors before this age is reasonable. Factors that increase the risk for osteoporosis in men include age (>70 years), low body weight (body mass index <20 to 25 kg/m2), weight loss (>10% [compared with the usual young or adult weight or weight loss in recent years]), physical inactivity (participates in no physical activities on a regular basis [walking, climbing stairs, carrying weights, housework, or gardening]), corticosteroid use, androgen deprivation therapy, and previous fragility fracture. Risk assessments should be updated periodically for men who choose not to be screened.

(2) Clinicians should obtain DXA for men who are at increased risk for osteoporosis and are candidates for drug therapy (Grade: strong recommendation; moderate-quality evidence).

> Bone density measurement with DXA is the accepted reference standard for diagnosing osteoporosis in men. Men who are at increased risk for osteoporosis are candidates for DXA. Little evidence about alternatives to DXA exists. The 2 most studied methods are quantitative ultrasonography (usually of the calcaneus) and the OST [Osteoporosis Self-Assessment Tool]. Available evidence indicates that neither alternative is sufficiently sensitive or specific at predicting DXA-determined bone mass to be recommended as a substitute for DXA. Although 1 study has demonstrated a strong relationship between calcaneal ultrasonography and subsequent fracture, until treatment trials establish the effectiveness of therapy for osteoporosis diagnosed by ultrasonography rather than DXA, the role of ultrasonography in initiating therapy remains uncertain. No studies have evaluated the optimal intervals for repeated screening by using BMD measurement with DXA.
>
> The evidence review showed that calcaneal ultrasonography predicts DXA-determined osteoporosis only modestly well. However, more important, it was a strong predictor of fracture in men. This may be because ultrasonography identifies other bone properties, such as bone quality, which may not be identified on DXA. Because treatment trials have not measured the effectiveness of therapy for osteoporosis diagnosed by ultrasonography rather than DXA, the role of ultrasonography in diagnosis remains uncertain.

In 2011, the USPSTF issued the following updated evidence-based recommendations for osteoporosis screening:[73]

(1) A grade B recommendation for screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors. In making this a grade B recommendation, the USPSTF offered the following rationale:

> No controlled studies have evaluated the effect of screening for osteoporosis on fracture rates or fracture-related morbidity or mortality.

[73] U.S. Preventive Services Task Force. Screening for osteoporosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2011;154(5):356-364.

> In postmenopausal women who have no previous osteoporotic fractures, the USPSTF found convincing evidence that drug therapies reduce the risk for fractures. In women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors, the USPSTF judged that the benefit of treating screening-detected osteoporosis is at least moderate.

(2) An I statement concluding that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.

> Because of the lack of relevant studies, the USPSTF found inadequate evidence that drug therapies reduce the risk for fractures in men who have no previous osteoporotic fractures. The USPSTF identified the absence of randomized trials of primary fracture prevention in men who have osteoporosis as a critical gap in the evidence.
>
> The USPSTF concludes that for men, evidence of the benefits of screening for osteoporosis is lacking and the balance of benefits and harms cannot be determined.

In discussing how often women should be screened for osteoporosis, the USPSTF noted the following:[74]

> The potential value of rescreening women whose initial screening test did not detect osteoporosis is to improve fracture risk prediction. Evidence is lacking about optimal intervals for repeated screening and whether repeated screening is necessary in a woman with normal BMD. Because of limitations in the precision of testing, a minimum of 2 years may be needed to reliably measure a change in BMD; however, longer intervals may be necessary to improve fracture risk prediction. A prospective study of 4124 women aged 65 years or older found that neither repeated BMD measurement nor the change in BMD after 8 years was more predictive of subsequent fracture risk than the original measurement.

In 2012, the American College of Obstetricians and Gynecologists (ACOG) issued the following updated evidence-based recommendations on screening women for osteoporosis:[75]

> Bone density screening for women should begin at age 65 years. DXA absorptiometry screening can be used selectively for women younger than 65 years if they are postmenopausal and have other significant risk factors for osteoporosis or fracture.

Regarding how often women should be screened for osteoporosis, the ACOG recommended the following:[76]

(1) In the absence of new risk factors, DXA screening should not be performed more frequently than every 2 years.

---

[74] *Ibid.*
[75] American College of Obstetricians and Gynecologists. Osteoporosis. September 17, 2012. http://www.guideline.gov/content.aspx?id=38413#Section420. Accessed January 7, 2015.
[76] *Ibid.*

(2) In the absence of new risk factors, DXA monitoring of therapy should not be repeated once bone mineral density (BMD) has been determined to be stable or improved.

In 2013, the National Osteoporosis Foundation (NOF) issued recommendations for BMD testing to screen for osteoporosis in the following groups:[77]

(1) Women age 65 and older.

(2) Men age 70 and older.

(3) Postmenopausal women and men age 50-69, with clinical risk factors for fracture.

The NOF also recommended that BMD testing be repeated 1 to 2 years after initiating therapy to reduce fracture risk and every two years thereafter.[78] It did not recommend annual screening for any group of individuals not initiating therapy for osteoporosis.

In summary, while the USPSTF and many other major medical professional organizations recommend screening certain high-risk individuals for osteoporosis, none recommend initial screening of low-risk individuals or annual screening of any individuals.

[77] National Osteoporosis Foundation. *2013 Clinician's Guide to Prevention and Treatment of Osteoporosis*. http://nof.org/files/nof/public/content/file/917/upload/481.pdf. Accessed January 7, 2015.
[78] *Ibid.*