January 22, 2015

Jessica L. Rich
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Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Mary K. Engle
Associate Director
Division of Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
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Dear Ms. Rich and Ms. Engle:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, is writing to request that the Federal Trade Commission (FTC) investigate the advertising and promotional activities of Life Line Screening, a for-profit company\(^1\) that uses direct-to-consumer marketing to promote inappropriately broad, nonselective cardiovascular disease and osteoporosis screening to people across the U.S. 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 cardiovascular disease and osteoporosis screening package and omit information material to consumers regarding the risks of adverse health-related outcomes and financial harms that may result from this indiscriminate screening.

Appendices A and B provide a detailed analysis explaining why the nonselective cardiovascular disease and osteoporosis screening programs promoted by Life Line Screening are medically inappropriate and unethical and can result in avoidable adverse health-related outcomes and financial harms.

**The FTC’s Legal Requirements for Advertising**

Sections 5 and 12 of the FTC Act prohibit advertisements that contain false or misleading representations or material omissions. The FTC Act broadly defines a “false advertisement” as

any “advertisement, other than labeling, which is misleading in a material respect,” whether
through affirmative “representations made or suggested” by the advertisement or through a
“fail[ure] to reveal facts material in light of such representations.”

When assessing whether advertising claims are deceptive, the FTC determines whether there is a
“reasonable basis” to support the claims. In explaining the reasonable-basis requirement, the
FTC noted the following:

The Commission intends to continue vigorous enforcement of this existing legal
requirement that advertisers substantiate express and implied claims, however conveyed,
that make objective assertions about the item or service advertised. Objective claims for
products or services represent explicitly or by implication that the advertiser has a
reasonable basis supporting these claims. These representations of substantiation are
material to consumers. That is, consumers would be less likely to rely on claims for
products and services if they knew the advertiser did not have a reasonable basis for
believing them to be true.[*] Therefore, a firm’s failure to possess and rely upon a
reasonable basis for objective claims constitutes an unfair and deceptive act or practice in
violation of Section 5 of the Federal Trade Commission Act.

[⁎] Nor presumably would an advertiser have made such claims unless the advertiser
thought they would be material to consumers.

According to the FTC, advertising claims fall into two basic categories for substantiation
purposes: efficacy and establishment claims. An efficacy claim “is a message that a given
product successfully performs the advertised benefit, such as preventing or treating a medical
condition.” The FTC applies a multifactor analysis, known as the Pfizer analysis, “to determine,
on a case-by-case basis, the level of substantiation needed for an efficacy claim.” The factors
considered in this analysis are: (1) the type of claim; (2) the type of product; (3) the benefits of a
truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a
false claim; and (6) the amount of substantiation experts in the field would agree is reasonable.

In contrast, an establishment claim “is a message that the advertiser has scientific evidence
backing up its efficacy claim.” The FTC does not apply the multifactor Pfizer analysis in
determining the substantiation needed for these claims: “Instead, [i]f an advertisement represents
that a particular claim has been scientifically established, the advertiser must possess a level of
proof sufficient to satisfy the relevant scientific community of the claim’s truth.”

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December 30, 2014.
4 Brief of Respondent FTC, POM Wonderful LLC v. FTC. D.C. Cir. No. 13-1060, at 6, filed March 25, 2014.
December 30, 2014.
5 See In re Pfizer Inc., 81 F.T.C. 23 (1972).
6 Ibid.
7 Brief of Respondent FTC, POM Wonderful v. FTC, at 7.
The FTC has emphasized that “it is particularly important to enforce substantiation requirements in the area of medical-benefit claims” because “[f]or centuries, many sellers of health products have made highly misleading claims that their products fight particular diseases, and they often cite ostensibly promising medical experiments that turn out to have been flawed or nonprobative. Such claims have nonetheless duped millions of consumers, in part because products sold for their medical benefits are ‘credence goods’ — products whose efficacy consumers cannot easily ascertain before or even after purchasing them.”

In the context of dietary supplements, the FTC “will closely scrutinize the scientific support that an advertiser cites as substantiation for a disease claim—i.e., for an advertisement that suggest[s], either directly or indirectly, that a product will provide a disease benefit.” The FTC “usually requires two well-controlled clinical tests” to substantiate generalized claims that scientific evidence supports a product’s purported medical benefits. The FTC has extended that substantiation requirement to simple efficacy claims.

The FTC is well aware that disease efficacy claims that are inadequately substantiated and inadequately qualified can harm consumers both financially and medically. With respect to financial harms, the FTC has noted that “like victims of any marketing fraud, consumers deceived into believing that a product will help prevent or treat diseases are more likely to buy the product and pay a premium for it than if they knew the whole truth.” Both financial and medical concerns independently justify the FTC’s long-standing insistence on rigorous scientific evidence for disease claims.

Public Citizen’s Assessment of Life Line Screening’s Advertising and Promotional Materials

Our review and analysis of Life Line Screening’s current website and recent print solicitations mailed directly to consumers’ homes found numerous medical-benefit efficacy claims that we believe to be deceptive because they are not substantiated by the level of evidence widely accepted in the medical community and by the FTC as necessary to support such claims: rigorous scientific evidence from well-controlled clinical tests of the company’s cardiovascular disease and osteoporosis screening tests in the broad consumer population targeted by Life Line Screening. The most egregious claims in this regard are those explicitly stating or strongly implying that the package of cardiovascular disease and osteoporosis screening tests offered by the company save lives, improve health, and prevent strokes and other cardiovascular diseases. Other statements made in Life Line Screening’s solicitations misleadingly assert that the company’s recommendations for screening are based on current medical guidelines. Key examples of such statements include 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*
Q. Why should I have these screenings done if I have no symptoms?
A. Many people are at risk for diseases such as stroke and heart disease but experience no symptoms. Early detection and control can prevent major consequences down the road. (http://www.lifelinescreening.com/Help-Center/FAQs/Screenings, accessed January 21, 2015; copy enclosed)

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. (solicitation letter from Life Line Screening advertising initial screening mailed directly to a consumer’s home in November 2014; copy enclosed)

As I’m sure you know, Stroke and Cardiovascular disease are among the leading causes of death in the United States – claiming almost 800,000 deaths a year. [underlining in original]

Many of these deaths are preventable. And since they often have no advance symptoms – it is critical to identify them before they become advanced.

Regular screenings help you keep on top of your vascular health, and ... can help you prevent strokes and cardiovascular disease.

(above three statements are from a solicitation letter from Life Line Screening promoting follow-up screening mailed directly to a consumer’s home in November 2014; copy enclosed)

Regular screenings can help you live a fuller, healthier life. [bold in original]
(solicitation letter from Life Line Screening promoting follow-up screening mailed directly to a consumer’s home in November 2014; copy enclosed)

We would not encourage you to take a screening if you wouldn’t benefit from it. Or recommend a test you don’t need. (solicitation letter from Life Line Screening promoting follow-up screening mailed directly to a consumer’s home in November 2014; copy enclosed)

Please see the enclosed chart for your Personalized Recommendation, based on current medical guidelines. [The enclosed chart recommends all five tests in Life Line Screening’s stroke, vascular, heart rhythm with osteoporosis screening package even though four screening tests performed on the targeted consumer in 2010 were normal and one — the carotid artery ultrasound — showed only mild plaque buildup.] (solicitation letter from Life Line Screening promoting follow-up screening mailed directly to a consumer’s home in November 2014; copy enclosed)

These statements claim that Life Line Screening’s package of cardiovascular disease and osteoporosis screening tests have helped save thousands of lives since 1993 and prevent strokes
and other types of cardiovascular disease. More broadly, such statements misleadingly imply that the company’s cardiovascular disease and osteoporosis screening package saves lives and prevent strokes and cardiovascular disease when used in unselected, asymptomatic individuals in the general population age 50 or older, regardless of their cardiovascular or osteoporosis risk factor profiles, which is the very consumer population targeted by Life Line Screening. We are not aware of any rigorous scientific evidence from well-controlled clinical tests substantiating such claims. Finally, current medical guidelines issued by major professional medical organizations do not support the type of initial or follow-up screening promoted by Life Line Screening.

Instead, to back up claims that its cardiovascular disease and osteoporosis screening tests save lives and prevent strokes and other cardiovascular disease, Life Line Screening appears to rely on testimonials and anecdotal reports from a small subset of people who were screened by the company, were found to have purportedly critical cardiovascular abnormalities, subsequently underwent some type of medical intervention, and survived without experiencing a stroke or other adverse cardiovascular events (see print and video testimonials at http://www.lifelinescreening.com/Success-Stories/Testimonials, http://www.lifelinescreening.com/Success-Stories, and http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For, accessed January 21, 2015; copies enclosed; also see enclosed Life Line Screening promotional materials mailed directly to a consumer’s home in November 2014). Such testimonials and reports from screened individuals fall far short of the level of evidence necessary to demonstrate that these cardiovascular screening tests are life-saving or prevent strokes and other adverse cardiovascular outcomes.

Substantiation of claims that disease screening tests save lives and prevent strokes and cardiovascular disease requires well-designed, prospective, randomized controlled clinical trials comparing long-term mortality, stroke, and cardiovascular disease rates in people who are screened with those in people who are not screened. With respect to Life Line Screening’s claims about its cardiovascular disease and osteoporosis screening tests, such evidence does not exist. And without that evidence, the efficacy claims made by Life Line Screening are misleading because they state as fact propositions that have not been proven.

Examples of other types of misleading statements found on Life Line Screening’s current website and in its online promotional materials are presented in Appendix C.

In addition, Life Line Screening’s advertising and promotional materials are further misleading because they omit important information material to consumers about (a) the type of individuals for whom particular cardiovascular disease and osteoporosis screening tests are clinically indicated; (b) evidence-based guidelines describing if and when such tests should be performed; and (c) the risks of cardiovascular disease and osteoporosis screening — particularly indiscriminate screening, as promoted by Life Line Screening — including the risks of adverse health-related outcomes and financial harms that can result from false-positive test results and from overdiagnosis (see Appendices A and B).
Requested Action

In summary, the inclusion of unsubstantiated medical-benefit efficacy claims about Life Line Screening’s cardiovascular disease and osteoporosis screening tests, combined with omissions of material information regarding the risks of these tests and the evidence-based guidelines describing their appropriate use, makes the company’s advertising and promotional materials deceptive. The company has relied on such materials to successfully dupe large numbers of consumers across the country into undergoing unnecessary and inappropriate cardiovascular disease and osteoporosis screening tests, exposing them to risks of adverse health-related outcomes and financial harms.

We therefore urge the FTC to investigate Life Line Screening’s advertising practices over the past two decades and demand that the company provide rigorous scientific evidence from well-controlled clinical tests to substantiate its numerous medical-benefit efficacy claims. The FTC should also assess other affirmative statements, such as those identified in Appendix C, and the omissions of material information discussed above that further contribute to Life Line Screening’s advertising and promotional materials being misleading. If your investigation finds these materials to be deceptive, we urge you to require that the company reimburse the millions of consumers who have purchased Life Line Screening’s unnecessary and medically inappropriate cardiovascular disease and osteoporosis screenings because of those materials.

Please note that this letter is posted on Public Citizen’s website, and you may publicly identify us as complainants in this matter to Life Line Screening or to any other parties.

Thank you for your prompt attention to this important patient safety and public health issue.

Sincerely,

Michael A. 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

Enclosures: Referenced Life Line Screening webpages
Life Line Screening’s print solicitation materials
Appendix A

Key Problems With the “Stroke, Vascular, Heart Rhythm with Osteoporosis” Screening Package Offered by Life Line Screening

(1) There is widespread consensus among medical experts that the package of four cardiovascular disease screening tests plus the screening test for osteoporosis advertised by Life Line Screening$^{14}$ 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 asymptomatic individuals promoted and provided by Life Line Screening for any one of these tests individually, let alone together as a package (see Appendix B 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 advertisements and solicitations that target consumer fear about having undetected, potentially life-threatening diseases.$^{15}$ 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.”$^{16}$ [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.”$^{17}$ [Emphasis added]

- Website: “Abdominal aortic aneurysms pose a threat because they are usually silent until a medical emergency occurs.”$^{18}$ [Emphasis added]

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$^{17}$ Ibid.

• 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.”19 [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 dangerously narrow. If a blood clot occurs in the carotid arteries, then blood cannot reach your brain and a stroke can result.”20 [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.”21 [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.”22 [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.”23 [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.”24 [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.”25 [Emphasis added]

• Direct-to-consumer letter:26 “What’s inside your arteries?” [Emphasis in original]

21 Ibid.
23 Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.
24 Ibid.
25 Ibid.
26 Ibid.
(3) For many people, false-positive test results from this screening lead to unfounded anxiety and additional unnecessary, risky, and costly diagnostic procedures and treatment interventions.\textsuperscript{27,28}

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 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.\textsuperscript{29} 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 to causing 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.\textsuperscript{30}

(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).\textsuperscript{31,32} Finally, direct-to-consumer promotional
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). \(^{33,34}\)

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Appendix B

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. 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. [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.” [Emphasis added]

The Life Line Screening promotional materials recommend that adults over age 50 undergo these
five screening tests annually:

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

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36 Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer.
Received November 2014.
38 Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer.
Received November 2014.
39 Life Line Screening. Atrial fibrillation screening. http://www.lifelinescreening.com/What-We-Do/What-We-
40 Life Line Screening. Carotid artery disease screening. http://www.lifelinescreening.com/What-We-Do/What-We-
42 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.
43 Life Line Screening. Osteoporosis screening/bone density test. http://www.lifelinescreening.com/What-We-
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.\(^4^4\)

The Life Line Screening package is offered at a price of $149, purportedly providing consumers a “savings of $181.”\(^4^5\)

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.

Although the following screening tests sound appealing, each one either: (a) clinically benefits only appropriately selected high-risk groups of patients (rather than \textit{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.

\textbf{A. Atrial fibrillation screening with electrocardiogram (ECG):}

The Life Line Screening online promotional materials state:\(^4^6\)

\begin{quote}
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.
\end{quote}

\(^{4^4}\) 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.

\(^{4^5}\) Undated letter from Kevin DeWeese, Director of Clinical Operations, Life Line Screening, to a consumer. Received November 2014.

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. The 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. 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

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primary health care providers by checking the pulse, followed by an ECG in case of irregularity.49,50

B. Stroke/Carotid Artery Ultrasound:

The Life Line Screening online promotional materials state:51

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. . .

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).52 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.53

In 2006, the AHA and the ASA issued a series of evidence-based guidelines for the primary prevention of stroke.54 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.

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.55 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.56 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.57 In making this a grade D recommendation, the USPSTF concluded with moderate

53 Ibid.
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.

**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. 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:

**Importance**

Stroke is a leading cause of death and disability in the United States. Although

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59 Ibid.
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% 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.60

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60 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
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, hypercholesterolemia, or known cardiovascular disease. 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:62

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. …

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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). 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. Thus, risk of AAA rupture rises with increasing size of the aneurysm. AAAs with a diameter between 3.0 and 3.9 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.

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. For men not screened for AAA, almost all deaths from ruptured AAAs occurred after age 65, with more than half occurring before age 80. For women not screened for AAA, the majority of AAA-related deaths occurred after age 80.

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:

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

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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 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 2013.70 The updated recommendations differ slightly from the 2005 recommendations and include the following:71

(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 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:

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

72 Ibid.
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 screening men as early as age 55 who have a family history of AAA. 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. 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.

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• **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 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:75

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

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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.76

In 2013, the USPSTF, based on a systematic review of the scientific literature,77 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.78 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.

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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 unselected adults (or generally asymptomatic adults) with ABI on cardiovascular disease or PAD health outcomes.79

E. Osteoporosis Screening/Bone Density Test

The Life Line Screening online promotional materials state:80

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.\textsuperscript{81}

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

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/m\textsuperscript{2}), 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:82

(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.

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:83

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

83 Ibid.
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:\textsuperscript{84}

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:\textsuperscript{85}

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

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:\textsuperscript{86}

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.\textsuperscript{87} 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.


\textsuperscript{85} Ibid.


\textsuperscript{87} Ibid.
Appendix C

Examples of Misleading Statements in Life Line Screening’s Promotional Materials

Life Line Screening’s statements are presented below in italics, followed by Public Citizen’s assessment of each.

- **9 Out Of 10 Doctors Support Screenings**: 9 out of 10 doctors support preventive health screenings for heart disease, stroke and other forms of atherosclerosis (plaque in the arteries) among patients with risk factors, but who otherwise show no symptoms. ([http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For](http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For), accessed January 21, 2015; copy enclosed)

This statement, which appears on multiple webpages on the Life Line Screening website, is misleading because it implies that 90 percent of all doctors support the type of cardiovascular disease screening promoted and provided by Life Line Screening. However, the statement includes a hyperlink to another page indicating that (a) the 90 percent statistic is based on interviews of 200 cardiovascular physicians, vascular surgeons, and neurologists conducted in July 2014 by Ebiquity Research Firm on behalf of Life Line Screening, and (b) 9 out of 10 of these interviewed physicians “believe preventive screening for cardiovascular disease can be a valuable health tool for patients who have two or more risk factors (i.e. age 55+, tobacco use, high-blood pressure, obesity, etc.).” Data from these interviews of 200 physicians in certain subspecialties — who likely were not selected randomly — are undoubtedly subject to significant bias and cannot be generalized to all cardiovascular physicians, vascular surgeons and neurologists, let alone to all physicians. Furthermore, a belief that preventive screening for cardiovascular disease can be a valuable health tool for certain at-risk patients cannot be construed as representing support for the type of annual screenings promoted by Life Line Screening.

- **Life Line Screening believes everyone should consider a prevention and wellness plan as a supplemental to their regular healthcare. This of course is different for every individual, and Life Line Screening works to ensure that each person is offered the screenings that are most beneficial and appropriate to their needs.**

**Life Line Screening’s Services Are Intended For Individuals With Relevant Health Risk Factors**

*Life Line Screening does not recommend every test we offer for everyone. Whether a test is right for you depends on your risk factors, your family history, your medical history, and your personal preferences regarding screening.*


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This statement is misleading because it implies that Life Line Screening carefully tailors its recommendations for cardiovascular disease and osteoporosis screenings based on the characteristics and risk-factor profile of each prospective customer. However, the Life Line Screening webpage for scheduling screening tests with the company routinely recommends that individuals undergo its heavily promoted screening package of four cardiovascular disease screenings (an electrocardiogram to screen for atrial fibrillation, a carotid artery ultrasound, an abdominal aortic aneurysm ultrasound and a peripheral arterial disease test) plus an osteoporosis risk assessment test (an ultrasound of the heel bone to measure bone mass density) regardless of an individual’s age (between age 50 and 80), gender, or cardiovascular disease or osteoporosis risk factors.⁸⁹

- *All of our ultrasound and EKG screenings are ... affordable. ...*  
  ([http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For](http://www.lifelinescreening.com/What-We-Do/What-We-Screen-For), accessed January 21, 2015; copy enclosed)

The statement that Life Line Screening’s screening tests are affordable is misleading. For most people being screened, the tests are not clinically indicated. For such people, any expenditure on such testing is a waste of money, not a savings. Therefore, the tests should not be construed as affordable.

Furthermore, for the minority of people for whom, because of age, symptoms, or other characteristics, one of the individual cardiovascular disease screening tests offered by Life Line Screening is clinically indicated, their health insurance likely would cover some or all of the costs of the testing when performed by another health care provider. For insured individuals, any out-of-pocket expense would likely be less than the fees that must be paid in advance to Life Line Screening when the screening tests are scheduled.

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⁸⁹ Life Line Screening. 8 million strong: Schedule online today.  
Enclosures: Referenced Life Line Screening webpages
Health Screening Services
(What-We-Do/What-We-Screen-For) / (What-We-Do) / (Who-We-Are) / (Success-Stories) / (Our-Partners)
800.449.2350 Schedule a Screening (http://secure.lifelinescreening.com/ecom/?sourcecd=WGGL999)

Clinical Team (Who-We-Are/Clinical-Team) Executive Team (Who-We-Are/Executive-Team)
Board of Directors (Who-We-Are/Board-of-Directors) Contact Us (Who-We-Are/Contact-Us)

Who We Are

At Life Line Screening, our mission is to make people aware of unrecognized health problems and encourage them to seek follow-up care with their personal physician. We are the leading provider of community-based preventive health screenings in the United States. We use advanced ultrasound equipment (the same as the equipment found in hospitals) and highly trained healthcare professionals perform our screenings. Board-certified physicians review each result to ensure the highest standards.

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. We are dedicated to providing the highest quality preventive screenings at affordable rates.
Health Screening Services

What We Do / Who We Are / Success Stories / Our Partners

800.449.2350  Schedule a Screening (http://secure.lifelinescreening.com/ecom/?sourcecd=WGGL999)

Privacy Policy (/Help-Center/Privacy-Policy)

Screenings

FAQs

Disease Information (/Help-Center/FAQs/Disease-Information)

- What is Heart Disease? (/Help-Center/FAQs/Disease-Information/Heart-Disease)
- What is Chronic Kidney Disease (CKD)? (/Help-Center/FAQs/Disease-Information/Kidney-Disease)
- What is Osteoporosis? (/Help-Center/FAQs/Disease-Information/Osteoporosis)
- What is Carotid Artery Disease? (/Help-Center/FAQs/Disease-Information/Stroke-Carotid-Artery)
- Understanding Health Screening Results (/Help-Center/FAQs/Results)
- Screenings (/Help-Center/FAQs/Screenings)
- What To Expect (/Help-Center/FAQs/What-To-Expect)
- Reimbursement (/Help-Center/FAQs/Reimbursement)

Frequently Asked Questions

Q. What is the objective of preventive health screenings?
Q. Why should I have these screenings done if I have no symptoms?

A. Many people are at risk for diseases such as stroke and heart disease but experience no symptoms. Early detection and control can prevent major consequences down the road.

Q. At what age should I be screened?

Q. How often should I have these general health screenings?

Q. How can your company afford to do these professional health screenings for such a low cost?

Q. Is Life Line Screening insured?

Q. How long has Life Line Screening offered these services?

Q. Is Life Line Screening a for-profit or not-for-profit organization?

Q. Are you affiliated with any hospital?

Q. I work during the day. Can I schedule a screening later in the day?

Q. I have a doctor. Why do I need Life Line Screening?

Q. Can my physician do this type of preventive health screening as part of my routine physical?

Q. Does Medicare or insurance cover professional health screenings?
Testimonials

Whether our screening participants were found to be at risk from peripheral arterial disease, carotid artery blockage, or another life-threatening disease, the one thing these participants all have in common is a powerful story about how Life Line Screening helped save their lives.
Colorado Man Finds That Even Construction Workers Can Get Osteoporosis

When Stephen Scudder found out he had a potentially serious condition, he and his wife, Joanne, weren't sure how they were going to explain it to people. After all, Stephen is extremely fit and active, with a job in construction that involves scrambling up ladders and hoisting sheets of plywood and other heavy objects by himself...

See more

Carotid Screening Helps Florida Woman Reduce Her Stroke Risk

Now that she looks back on the past year, Suzanne Robinson realizes that she wasn't feeling quite well. When she would tilt her head back while putting items on an upper shelf, she would have a dizzy spell. Then in early spring of 2008, she developed double vision...

See more
Our Chief Medical Officer, Dr. Andy Manganaro explains our commitment to medical science and healthier lives.

Learn More

Ken Goins
"My doctor told me to go ahead and do the screening because she had three other patients whose lives were saved by the process."

Helen Anderson
"We highly recommend that everyone take part in the Life Line Screening tests. It may save your life as it did my husband's. His abdominal aortic aneurysm could have ruptured."
Discover real stories and testimonials about people from across the country whose lives were positively impacted by Life Line Screening.

We've screened more than eight million people and for many, the experience was life changing. Watch as real Life Line Screening customers share their stories.

Watch the videos below or read personal testimonials (/Success%20Stories/Testimonials.aspx) for a small sampling of the powerful stories our health screening participants have shared with us.

**Share your own story with us** (http://www.lifelinescreening.com/about-us/personal-stories/share-your-story.aspx)
Testimonials

Read powerful stories about how Life Line Screening changed the lives of those with life-threatening conditions. Browse testimonials now

Read More (/Success-Stories/Testimonials)

Sam and Carol Raines

"My surgeon was amazed and told me that if the Life Line

Lynn Hagelshaw

"The doctor said that the blockage was even more severe than he had thought previously and that a stroke
Screening had not detected the problem, I would have probably suffered a massive stroke or even fatal consequences." — Sam Raines

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Rebecca Davis

"The surgeon told me it was the best money that I had ever spent in my life."
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Newsletter Signup

Sign Up For Email Updates and Save 10% Off Your First Screening.

First Name

Email

Zip Code

Sign Up Now

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National Foundation for Cancer Research
Health Screening Services

What To Expect  
Screening Packages  
What Experts Say About Cardiovascular Disease  
Our Commitment  
About Your Results  

Schedule a Screening
Testosterone Deficiency Screening (What-We-Do/What-We-Screen-For/Testosterone)
Vitamin D Screening (What-We-Do/What-We-Screen-For/Vitamin-D)
Heart Disease Screening (What-We-Do/What-We-Screen-For/Heart-Disease)
Congestive Heart Failure Screening (What-We-Do/What-We-Screen-For/Congestive-Heart-Failure)
Carotid Artery Disease Screening (What-We-Do/What-We-Screen-For/Carotid-Artery-Disease)
High Cholesterol Screening/Lipid Panel Test (What-We-Do/What-We-Screen-For/High-Cholesterol)
Chronic Obstructive Pulmonary Disease (COPD) Screening (What-We-Do/What-We-Screen-For/COPD)
Atrial Fibrillation Screening (What-We-Do/What-We-Screen-For/Atrial-Fibrillation)
C-Reactive Protein Screening (What-We-Do/What-We-Screen-For/C-Reactive-Protein)
Lung Cancer Screening (What-We-Do/What-We-Screen-For/Lung-Cancer)
Abdominal Aortic Aneurysm Screening (What-We-Do/What-We-Screen-For/Abdominal-Aortic-Aneurysms)
Health Risk Assessment - 6 for Life (What-We-Do/What-We-Screen-For/6-for-Life)
Type 2 Diabetes Screening (What-We-Do/What-We-Screen-For/Type-2-Diabetes)
Osteoporosis Screening/Bone Density Test (What-We-Do/What-We-Screen-For/Osteoporosis)
Peripheral Arterial Disease Screening (What-We-Do/What-We-Screen-For/Peripheral-Arterial-Disease)
Elevated Liver Enzymes Screening (What-We-Do/What-We-Screen-For/Elevated-Liver-Enzymes)
Chronic Kidney Disease (CKD) Screening (What-We-Do/What-We-Screen-For/Chronic-Kidney-Disease)
High Blood Pressure (What-We-Do/What-We-Screen-For/High-Blood-Pressure)
Prostate Cancer Screening (What-We-Do/What-We-Screen-For/Prostate-Cancer)
Thyroid Disease Screening (What-We-Do/What-We-Screen-For/Thyroid-Disease)
Colorectal Cancer Screening (What-We-Do/What-We-Screen-For/Colorectal-Cancer)

All of our ultrasound and EKG screenings are easy, painless, affordable, and convenient. Our highly trained technologists use state-of-the-art ultrasound screening equipment for lab-accurate results. In addition, our screenings require very little or no preparation.
There are 3 types of preventive health screenings.

Ultrasound screenings

Ultrasound (also called sonography) is a technique that uses sound waves to image structures in the body. During the ultrasound, high-frequency sound waves are transmitted to the area of interest in the body and the returning echoes are recorded.

First developed in World War II to locate submerged objects, ultrasound is now widely used to detect or monitor medical conditions in such areas as obstetrics, ophthalmology, and cardiology. Most people are familiar with it related to seeing the growing fetus during pregnancy. Ultrasound is painless and non-invasive.

Life Line Screening utilizes state-of-the-art Doppler color flow ultrasound technology. You can count on this equipment for accurate, reliable images for:

- Abdominal aortic aneurysm screening
- Carotid artery disease screening
- Ankle-brachial index screening (for peripheral arterial disease)
- Bone mineral density screening (for osteoporosis risk)

Finger-stick blood screenings

In select locations, we offer simple finger-stick blood screenings that identify important risk factors for heart disease and diabetes.

These screenings are conducted by pricking the soft pad of the finger and taking a few drops of blood. The instruments we use to perform the blood screenings are FDA-approved, lab-accurate, and are used throughout the country by major hospitals, insurance companies, pharmaceutical companies, and laboratories. Results are provided in less than 10 minutes.

Life Line Screening offers the following blood screenings:

- Complete lipid panel screening — Measures total cholesterol, HDL ("good" cholesterol), LDL ("bad" cholesterol), and triglycerides.
- Glucose screening — Measures blood sugar levels to assess diabetes risk.
- High-sensitivity C-reactive protein (hs-CRP) screening — Measures levels of C-reactive protein, an indicator for cardiovascular disease.
- Elevated liver enzymes (ALT/AST) screening — Measures levels of ALT and AST liver enzymes, an indicator of liver injury.

Limited electrocardiograph

To detect atrial fibrillation, also known as irregular heartbeat, a common heart condition that significantly increases the risk of stroke, we conduct an EKG. Our EKG electrode screening is quick, non-invasive and
requires no preparation or removal of clothing.

9 Out Of 10 Doctors Support Screenings

9 out of 10 doctors support preventive health screenings for heart disease, stroke and other forms of atherosclerosis (plaque in the arteries) among patients with risk factors, but who otherwise show no symptoms.

Our Commitment to Science

Our Chief Medical Officer, Dr. Andy Manganaro explains our commitment to medical science and healthier lives.

Learn More

Learn More

Patrice Falls and Michelle Acquista

"I am so thankful that the screening caught that blockage and saved my sister's life. I am now passing this information to everyone and getting all my family and friends to go." — Patrice Falls
The Larry King Cardiac Foundation

The Larry King Cardiac Foundation (LKCF) was established in 1988, to help facilitate life-saving treatment for individuals who, due to limited means or no insurance, would otherwise be unable to receive care.
Our Commitment

Prevention & Wellness Is Where Healthcare Should Start

Life Line Screening believes everyone should consider a prevention and wellness plan as a supplemental to their regular healthcare. This of course is different for every individual, and Life Line Screening works to ensure that each person is offered the screenings that are most beneficial and appropriate to their needs.
Life Line Screening's Services Are Intended For Individuals With Relevant Health Risk Factors

Life Line Screening does not recommend every test we offer for everyone. Whether a test is right for you depends on your risk factors, your family history, your medical history, and your personal preferences regarding screening.

A Specific Note About Vascular Tests

We recommend these tests for individuals with identified risk factors for present or future cardiovascular diseases such as heart attack and stroke—major causes of death and disability in the United States. Risk factors include: being age 55 or over, high blood pressure, high cholesterol, diabetes, obesity, a history of smoking, a family history of stroke or heart attack in a mother, father, sister or brother, and a personal medical history of other cardiovascular issues. The presence of some or all of these risk factors increases the likelihood that cardiovascular disease (as a result of what is called atherosclerosis or "hardening of the arteries") may occur. Early identification of atherosclerosis is important in allowing you and your doctor to make changes in your life which may prevent the development and progression of these potentially life threatening illnesses.

Medical Science Is Constantly Evolving
Enclosures: Examples of Life Line Screening's print solicitation materials mailed directly to consumers' homes
Dear [NAME]

What would your doctor say...if he/she could actually see inside your arteries?

Now it’s possible with a simple ultrasound screening that can reveal dangerous plaque buildup or blockage, from Life Line Screening.

These screenings have proven to be safe and accurate in detecting your risks for stroke and vascular disease — so you and your doctor can do something about it before it’s too late.

Local screenings will be held on December 11, 2014 at [LOCATION]. In fact, this event is sponsored by Minimally Invasive Vascular Centers. Call 1-800-772-8215 now to register.

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.†

And many people who suffer from them experience...

(over, please)


Life Line Screening will be in your area on December 11, 2014

Reserved for: [NAME]

Location: [LOCATION]

PRIORITY CODE: [CODE]

IMPORTANT:
You must call 1-800-772-8215 to register.

Directions will be provided when you register for your screening.

Plaque build-up reduces your blood flow and can be dangerous if left untreated.

Normal artery allows blood to flow through easily

As you age, arteries can become partially blocked or even collapse.
...no prior symptoms or warning signs.

That’s why so many doctors have recommended Life Line Screening to their patients. Last year alone, over 7,000 Life Line Screening customers reported that their doctors recommended Life Line Screening.

All screenings are provided right in your community, starting as low as $60 each. You can also receive all five recommended screenings for the special price of only $149 — and save $181. These include:

- Stroke/Carotid Artery Screening
- Heart Rhythm Screening (Atrial Fibrillation)
- Abdominal Aortic Aneurysm Screening
- Peripheral Arterial Disease Screening
- Osteoporosis Risk Assessment

The screenings will take only about one hour of your time, and you will be notified if you have an immediate problem*.

A Trusted Partner

Life Line Screening has conducted nearly 8 million screenings, and customers sometimes tell us that they feel the screenings saved their lives.

Life Line Screening is coming to your area for one day only. There are only a limited number of available appointments, and advance registration is required.

What’s inside your arteries? Call 1-800-772-8215 now to schedule your screening.

Sincerely,

Kevin DeWeese, RDCS, RVS
Director of Clinical Operations, Life Line Screening

P.S. These are the same screenings that your doctor could order for you, but they typically will not be paid for by insurance unless you already have symptoms.

*in most States
Questions & Answers about Life Line Screening

Q. Who needs to be screened?
A. The answer is anyone over 50 who wants to be proactive about his or her health. The National Stroke Association (NSA) states that your risk of stroke doubles each decade after age 55.

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 of exercise, you may wish to be screened, even if you are in your 40’s.

Q. Can’t my doctor do these screenings?
A. These are the same screenings that your doctor could order for you, but they typically will not be paid for by insurance unless you already have symptoms. Life Line Screening performs these screenings conveniently, allowing you to get screened whenever you choose, and the tests are offered at a lower cost – making them affordable, even without insurance. Life Line Screening’s goal is to identify individuals with significant disease before a problem occurs.

Q. How long does it take?
A. Each health screening generally takes about 10 minutes. If you are having these five screenings, Life Line Screening recommends you allocate a little more than an hour.

Q. When will I learn the results?
A. If Life Line Screening finds a condition that is life-threatening, they will notify you on the day of the screenings, so you can consult your physician immediately.* If not, then your screening will be carefully reviewed by one of their board certified physicians, and you will receive your results within 21 days.

Q. How much does it cost?
A. Most people are surprised at the low cost of these screenings. However, the 5 screenings described in this letter can be completed for $149. A savings of $181.

Q. Are they covered by Medicare or health insurance?
A. Medicare and health insurance generally do not allow for coverage of vascular screenings. Insurance coverage varies from policy to policy. However, Life Line Screening will provide you with a detailed receipt that can be submitted to your insurance company to determine coverage. You should also make a copy of your results to send along.

Q. Which screenings will be performed?
A. The five we recommend are:

• Stroke/Carotid Artery Screening
• Heart Rhythm Screening (Atrial Fibrillation)
• Abdominal Aortic Aneurysm Screening
• Peripheral Arterial Disease Screening
• Osteoporosis Risk Assessment

Q. I’m convinced. What’s my next step?
A. Life Line Screening will be in your area for one day only. And pre-registration is required. Please call as soon as possible to ensure that we can allocate the time for your screening.

*In most states
What do doctors have to say about these preventive health screenings?

Your doctor can confirm the value and importance of these screenings, when it comes to identifying your risks for stroke, aneurysm and vascular disease.

"After my wife insisted that I go and have a Life Line Screening, it showed a buildup of plaque in my carotid artery. My doctor said I would have suffered a stroke. It saved my life."

Lindsey King, South Holland, IL

"I presented the results to my heart specialist who entered the reports into my medical records."

Kenneth MacLean, San Diego, CA

"When I shared my Life Line Screening results with my doctor he said, 'I wish all my patients did this because we could eliminate so many problems ahead of time.'"

Eva Watson, Levelland, TX

"My doctor followed up on the results of your screening, which led to a diagnosis of PAD. I will say that it was a Godsend to me. I just feel like this saved my life. I just think that it did."

Ms. Wilda Stough, Geneva, AL

"The surgeon stated that the warning signs from the Life Line Screening process, and dad's proactive efforts in obtaining the ultrasound, certainly saved his life."

Patricia Clarke, Carlsbad, CA
Questions & Answers about Life Line Screening

Q. Who needs to be screened?
A. The answer is anyone over 50 who wants to be proactive about his or her health. The National Stroke Association (NSA) states that your risk of stroke doubles every decade after age 55. However if you have a family history of stroke or heart disease, or if you have high risk factors such as being overweight, smoking, or lack of exercise, you may wish to be screened, even if you are in your 40s.

Q. Can’t my doctor do these screenings?
A. These are the same screenings that your doctor could order for you, but they typically will not be paid for by insurance unless you already have symptoms. Life Line Screening performs these screenings conveniently, allowing you to get screened whenever you choose, and the test are offered at a lower cost - making them affordable, even without insurance. Our goal is to identify individuals with significant disease through the screening process, before a problem occurs.

Q. Are they covered by Medicare or health insurance?
A. Medicare and health insurance generally does not allow for coverage of vascular screenings. Insurance coverage varies from policy to policy. However, we will provide you with a detailed receipt that can be submitted to your insurance company to determine coverage. You should also make a copy of your results to send along.

Q. How much does it cost?
A. Most people are surprised at the low cost of these screenings. However, we do so many of them, it is possible to keep our costs down. The 5 screenings described below can be completed for only $149.

Q. Which screenings will be performed?
A. The five that we recommend are:
   • Stroke/Carotid Artery Screening
   • Heart Rhythm Screening (Atrial Fibrillation)
   • Abdominal Aortic Aneurysm Screening
   • Peripheral Arterial Disease Screening
   • Osteoporosis Risk Assessment

Q. How long does it take?
A. Each health screening generally takes about 10 minutes. If you are having these five screenings, we recommend you allocate a little more than an hour.

Q. When will I learn the results?
A. If we find a condition that is life-threatening, we will notify you on the day of the screening, so you can consult your physician immediately.* If not, then your screening will be carefully reviewed by one of our board certified physicians, and you will receive your results within 21 days.

Q. I’m convinced. What’s my next step?
A. Life Line Screening will be in your area for one day only. And pre-registration is required. Please call as soon as possible to ensure that we can allocate the time for your screening.

*In most states
1 Stroke/Carotid Artery Screening
Ultrasound evaluation of the carotid arteries that screens for buildup of fatty plaque — a leading cause of strokes.

2 Heart Rhythm Screening
(Atrial Fibrillation)
A quick and easy test using EKG electrodes placed on the arms and legs to identify the presence or absence of an irregular heartbeat. Atrial Fibrillation increases the risk of stroke 5 times.

3 Abdominal Aortic Aneurysm Screening
Ultrasound is used to screen for the presence of an aneurysm (enlargement) in the abdominal aorta that could lead to a ruptured aorta.

4 Peripheral Arterial Disease Screening
Evaluates for peripheral arterial disease (plaque buildup) in the lower extremities. Patients with PAD (peripheral arterial disease) are 3 to 6 times more likely to have a heart attack or stroke.

5 Osteoporosis Risk Assessment
An ultrasound measurement of the heel bone to determine abnormal bone mass density in men and women. Osteoporosis is painless and silent in its early stages.

“When I shared my Life Line Screening results with my doctor, he said, ‘Oh my goodness. I wish all of my patients did this because we could eliminate so many problems by knowing ahead of time.’

— E. Watson, Levelland, TX

“I was skeptical about your services but finally decided to give them a try. My left carotid artery was severely blocked and my right one was partially blocked.

My original doctor dismissed the findings and didn’t do anything about it.

But this just didn’t feel right to me so I found another doctor. By this time I had a few pins and needles in my arm. My doctor followed up and sent me to a vascular surgeon. I am only 56 years old, so the surgeon was surprised by the level of blockage I already had at such a young age. He indicated that this type of fast building blockage is genetic and it is important I have it taken care of. He told me I would have a stroke within a year if I did not address it right now.

My surgery was scheduled for several weeks later, but I never made it that long. While I was by myself, I noticed that I had numbness in my left arm. This went on for 30-40 minutes. Knowing I had a blockage and that numbness could be the sign of a stroke, I went to the emergency room. I was having a small stroke called a Transient-Ischemic Attack, a TIA. So we moved the surgery up 3 weeks and when the surgeon got in there he said it was worse than he had thought.

There is no doubt that Life Line Screening saved my life. That was the best $150 I ever spent.”

— G. Stowe, Venetia, PA

www.lifelinescreening.com/learnmore

Pre-registration is required.
Call 1-800-772-8215

Priority Code: MMPA-023

Park Center Plaza II
6150 Oak Tree Blvd.
Independence, OH 44131
Your Personalized Prevention Plan is Enclosed!

ROUTINE HEALTH SCREENINGS CAN IDENTIFY YOUR RISKS.

Trusted by hospitals nationwide, we screen almost one million people at over 15,000 locations each year.
Dear [Name],

The following medical information is private and confidential:

Your previous Life Line Screening was back on April [date], 2010 and results indicated a mild/moderate Carotid Artery blockage. You should be re-screened now to determine if this has changed.

As a result, we feel you would benefit from 5 specific follow-up screenings at this time.

Please see the enclosed chart for your Personalized Recommendation, based on current medical guidelines.

Preventive health maintenance is important because the root cause of the majority of these conditions is plaque buildup in your arteries, which continues to happen silently as you age.

As I'm sure you know, Stroke and Cardiovascular disease are among the leading causes of death in the United States - claiming almost 800,000 deaths a year.†

Many of these deaths are preventable. And since they often have no advance symptoms - it is critical to identify them before they become advanced.

Regular screenings help you keep on top of your vascular health, and...

(over, please)

† Source: Centers for Disease Control and Prevention
...can help you prevent strokes and cardiovascular disease.

And the best part is our screenings are quick, painless, non-invasive and you don’t even have to remove your clothing.

Please note, we do not recommend every test with each visit

We would not encourage you to take a screening if you wouldn’t benefit from it. Or recommend a test you don’t need.

And we understand that cost can be an issue – even though we have worked hard to keep our costs less than what you’d pay for virtually any medical procedure.

That’s why we urge you to read your Personalized Recommendation Chart to see what screenings are recommended at this time. And if you have not yet done so, we encourage you to share this information with your doctor.

Regular screenings can help you live a fuller, healthier life

I can’t put it more simply than that. We are all lucky enough to live in a time when life threatening diseases can be detected – even without any symptoms – so that you and your doctor can do something about them.

I urge you to take advantage of our regular screening program, and schedule your next appointment as soon as possible.

Sincerely,

Kevin DeWeese, RDCS, RVS
Director of Clinical Operations, Life Line Screening

P.S. Remember: we will be in your area for one day only. Please call us today.
Your test results from your screening on April 15, 2010 indicate that you are due for 5 screenings.

For only $139 you can have all 5 recommended tests:

<table>
<thead>
<tr>
<th>Screening</th>
<th>Previous Result</th>
<th>Recommended Now?</th>
<th>Reason Why</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Artery (Plaque)</td>
<td>ABNORMAL (MILD plaque buildup)</td>
<td>YES</td>
<td>Your last screening revealed mild plaque buildup and was performed more than 12 months ago.</td>
</tr>
<tr>
<td>Heart Rhythm (Atrial Fibrillation)</td>
<td>NORMAL</td>
<td>YES</td>
<td>Your last screening was normal but performed more than 12 months ago.</td>
</tr>
<tr>
<td>Abdominal Aortic Aneurysm</td>
<td>NORMAL (&lt; 3cm)</td>
<td>YES</td>
<td>Your last screening was normal (AAA &lt; 3cm) but performed more than 3 years ago.</td>
</tr>
<tr>
<td>Peripheral Arterial Disease</td>
<td>NORMAL (Ankle-Brachial Index ≥0.90)</td>
<td>YES</td>
<td>Your last screening was normal (ABI ≥ 0.90) but performed more than 12 months ago.</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>NORMAL</td>
<td>YES</td>
<td>Your last screening was normal but performed more than 2 years ago.</td>
</tr>
</tbody>
</table>

Please don't postpone these important screenings. Cardiovascular disease is the #1 cause of death in men and women in the United States - and a leading cause of adult disability. And the National Stroke Association (NSA) states that your risk of stroke doubles when you reach your 50s. Unfortunately, many significant vascular problems go undetected until it is too late. And Life Line Screening will be in your area for one day only.

Important: You must call 1.877.379.4726 to register.  

Priority Code: [blank]
Questions & Answers about Regular Screening

Q. Who needs to be screened regularly?
A. You do – The National Stroke Association (NSA) states that your risk of stroke doubles each decade after age 55.

However, it is especially important to be re-screened if your previous tests revealed any risk factors. Or if you have a family history of heart disease, stroke or diabetes.

Q. Which screenings will be performed?
A. These will be based on your previous results and medical guidelines. They may include:

- Carotid Artery Screening (Plaque)
- Abdominal Aortic Aneurysm Screening
- Osteoporosis Risk Assessment
- Heart Rhythm Screening (Atrial Fibrillation)
- Peripheral Arterial Disease Screening
- 6 for Life Health Assessment
- Plus any important tests that you may not have taken when you were first screened.

Q. How long does it take?
A. The professional health screenings generally take a little more than an hour. We recommend you allocate this amount of time for your next screening appointment.

Q. Will insurance cover these screenings?
A. Though your doctor may order preventive screenings, generally insurance providers do not cover them unless you are showing symptoms. Unfortunately more than 80% of all people who suffer a stroke show no apparent symptoms or warning signs.

That’s why Life Line Screening helps to bridge this gap by offering community-based screenings at an affordable price.

Q. What do health care professionals say?
A. We encourage you to ask your doctor about preventive health screenings and what they can tell you about your health.

Q. Can’t my doctor do these screenings?
A. Most physicians can only order diagnostic tests if you are experiencing symptoms. They are usually not able to order them as a preventive measure because insurance will not cover them. Our goal is to identify individuals with significant disease through the screening process, before a problem occurs.

Q. Can I bring along a friend or spouse?
A. Absolutely – you will be doing them an important favor. However, Life Line Screening will be in your area for one day only. And pre-registration is required. Please call as soon as possible to register for an appointment today.
Your health changes with age
As you get older, your risks for stroke and cardiovascular disease naturally increases – even if you maintain a healthy lifestyle.

The National Stroke Association (NSA) states that your risk of stroke doubles every decade after age 55.

You may not be aware of any symptoms
These changes – which can greatly increase your risks – often occur without any symptoms. That is why regular screenings are so important.

A preventive ultrasound screening may identify potential life threatening problems early enough for your physician to take action.

We’ve identified thousands potentially at risk
Life Line Screening identified over 62,000 people who had potentially serious health risks for stroke or cardiovascular disease but showed no apparent symptoms, within the last year alone.

If we find a condition that needs immediate attention, we will notify you on the day of the screening, so you can consult your physician immediately.

All it takes is a little more than an hour
That’s less time than you’d take to go to dinner, watch your favorite TV show, or spend at your gym, but it can provide valuable information regarding your health.

You’ll also have the peace-of-mind knowing that you are monitoring and managing your risks for stroke and heart disease.
Your health changes with age
As you get older, your risks for stroke and cardiovascular disease naturally increases – even if you maintain a healthy lifestyle.

The National Stroke Association (NSA) states that your risk of stroke doubles every decade after age 55.

You may not be aware of any symptoms
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We’ve identified thousands potentially at risk
Life Line Screening identified over 62,000 people who had potentially serious health risks for stroke or cardiovascular disease but showed no apparent symptoms, within the last year alone.

If we find a condition that needs immediate attention, we will notify you on the day

**this is what your annual check-up may **NOT** reveal.**

- This is a normal artery that allows blood to flow through easily.
- **YOU ARE HERE** Your last screening revealed mild/moderate results which means your arteries are partially blocked.
- If left untreated, your arteries can become even more blocked, which can be dangerous.
Disease risks can be reduced – if detected by your physician

Trusted by Hospitals Nationwide
Life Line Screening has partnered with hospitals across the country. Our staff includes board certified vascular surgeons, cardiologists, and radiologists. And we use the same state-of-the-art Doppler ultrasound technology found in most hospitals.

We’ve screened nearly 8 million Americans
Life Line Screening is the nation’s leader in providing community-based preventive health screenings. We’re committed to helping people manage and monitor their wellness – by coming to their neighborhoods, and offering painless, non-invasive and affordable screenings.

We’ve identified thousands potentially at risk
We strongly believe in the power of prevention. Last year alone, Life Line Screening identified more than 62,000 people who had potentially serious health risks for stroke or cardiovascular disease but showed no apparent symptoms.
Disease risks can be reduced – if detected by your physician

Trusted by Hospitals Nationwide
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We’ve screened nearly 8 million Americans

SCREENING DATE:

please register your screening for 2015

Please call 1-877-379-4726

Priority Code:

SCREENING LOCATION:
“Regular screenings saved my life.”

“I literally owe my life to you. You found a mild blockage a couple of years ago and for some reason, I forgot about it. You called to remind me that it was time to come back and that this was a problem that should be monitored. This time the blockage was really significant. I had an operation which truly saved my life, according to my doctors.”

—E. Watson, Levelland, TX

“I can’t thank Life Line Screening enough for making me aware of what could have been a serious problem.”

—Russ Klingel, St. Louis, MO

“My husband had an AAA and is doing well. I just wanted to thank you for helping us.”

—Sharon Reilly, N. Aurora, IL

“When I shared my Life Line Screening results with my doctor, he said, ‘Oh my goodness. I wish all of my patients did this because we could eliminate so many problems by knowing ahead of time.’”

—E. Watson, Levelland, TX

“As a spouse and RN I cannot say how glad I am that we had this test done! There is a huge history of vessel and heart disease in Loren’s family, and I am so thankful it was discovered before he had a major stroke.”

—Pat Buls, Waterloo, IA

Life Line Screenings has been a Better Business Bureau Accredited Business since 1996. The BBB letter grades represent the BBB’s opinion of the business. An A+ rating is the highest rating a business can receive. Our standards are high and this shows in all aspects of our business.