



American
Heart
Association.



PAD

NATIONAL ACTION PLAN

Dear Stakeholders:

Did you know that peripheral artery disease (PAD) afflicts 8-10 million people in the United States and causes about 150,000 nontraumatic amputations annually?¹ PAD also can impact quality of life and present mortality risk that is even more dramatic with advanced disease, often characterized by nonhealing leg ulcers or limb-threatening ischemia. Furthermore, there are striking racial and socioeconomic disparities in U.S. amputation rates. Yet many Americans — even some clinicians — remain unaware of the disease and its devastating impact on individuals, their families and communities.

Because this preventable, treatable condition causes so much unnecessary suffering and death, we created the PAD National Action Plan — a road map for a coordinated, enduring approach to vascular health. This will be the first step in a long journey of change. Our forward-looking Action Plan is designed to transform our approach to PAD and save lives.

The PAD National Action Plan represents a collaborative effort on behalf of the American Heart Association and collaborating organizations (see page 51). We convened a PAD Roundtable in December 2018 at the National Heart, Lung, and Blood Institute with 50 participants including health care professionals, governmental organizations, nonprofit organizations, patient advocacy groups and PAD patients. The attendees developed strategic goals, actions and tactics that were refined at a PAD Summit in April 2021 into the PAD National Action Plan.

Six strategic goals to improve the awareness, diagnosis and treatment of PAD are described in the following pages, each with up to six essential tactics for success. A crosscutting theme is inequity — in diagnosis and treatment of PAD — by race, ethnicity, socioeconomic status and sex. For example, the lifetime risk of PAD is three times higher in Black Americans compared to non-Hispanic White Americans, even when accounting for the differential prevalence of risk factors such as diabetes, hypertension and smoking.² The Action Plan also outlines approaches to enhance PAD prevention, diagnosis and treatment today while highlighting the many gaps and opportunities in PAD research to further reduce preventable complications and deaths for future generations.

The PAD National Action Plan is a thoughtful guide that will enable us as a nation to coordinate interventions for prevention of PAD complications, treatment of cardiovascular risk and improvement of quality of life for those living with the disease. But its long-term success depends on the synergistic action of many groups committed to addressing PAD. To implement the Action Plan successfully, we require input, funding and sustained collaboration. Together, we can make a lasting impact on vascular health to save both limbs and lives.



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Why a PAD National Action Plan — And Why Now?

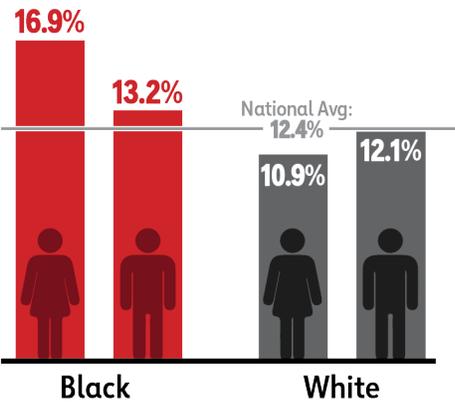
Peripheral artery disease (PAD) is a progressive atherosclerotic disease, in which one or more peripheral arteries, typically in the lower limbs, are partially or completely obstructed.^{3,4}

HIGH PREVALENCE AND GROWING INCIDENCE

PAD afflicts 8-10 million people in the United States, the majority of whom are age 65 years and older.⁵ A recent analysis⁶ of Medicare claims spanning 2003-2012 estimated a mean annual prevalence of 12.4% for diagnosed PAD. The prevalence is significantly higher in Black women and men in the United States (16.9% and 13.2%, respectively) compared to White women and men (10.9% and 12.1%, respectively). These numbers are consistent with the recently projected ~30% cumulative lifetime risk of PAD for Black Americans⁷ but do not account for cases of PAD that remain undetected due to low patient and clinician awareness. As the U.S. population ages, by 2050 an estimated 19 million people will have PAD, and an estimated 16 million of those will be 65 years and older.⁸

Annual prevalence of diagnosed PAD

— by race & sex —



SIGNIFICANT MORBIDITY

Lower extremity PAD is associated with significantly reduced function and quality of life, increased risk of hospitalization and amputation, high mortality, and high cost of care.^{9,10} In addition, a recent report indicated a 50% increase in nontraumatic lower extremity amputations between 2009 and 2015 among individuals with diabetes.¹¹ Overall, approximately one-third of patients will die within five years of a PAD diagnosis and 20% will experience a myocardial infarction or stroke.¹²

UNDERTREATMENT

Many of the same conditions that contribute to coronary artery disease (CAD) are also implicated in the development of PAD and its progression, including cigarette smoking, diabetes, hypercholesterolemia and hypertension.⁴ People with PAD often have vascular disease in other territories, including the heart and brain, and these patients with polyvascular disease have the highest risk of events and greatest potential benefit from treatment. However, even patients with clinically diagnosed PAD are not treated as frequently as patients with clinically diagnosed CAD with guideline directed medical therapy, such as statins or anti-platelet agents.^{13,14} Health disparities and a lack of knowledge among both patients and health care professionals about the standards for prevention, early detection and management of PAD also contribute to undertreatment.^{8,13-18}

LOW AWARENESS

Despite its relatively high prevalence, there is a significant gap in the public's understanding of the symptoms and complications of the condition. In a 2006 telephone survey¹⁹ of 2,500 adults 50 and older, only 26% were familiar with PAD compared with more than 65% familiar with CAD, cerebrovascular disease and heart failure. Just 14% knew that PAD could lead to amputation and 25% were aware that the condition was linked to a higher risk of myocardial infarction and stroke. Contemporary data are greatly needed to establish benchmarks for newly deployed

14% knew that PAD could lead to **amputations**

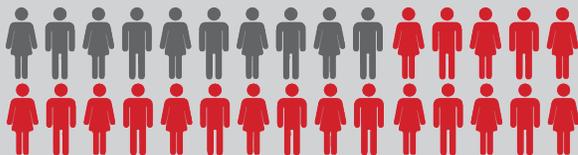


25% knew that PAD was linked to a higher risk of **myocardial infarction & stroke**



campaigns to address this issue. A similar knowledge gap exists among physicians with many PAD diagnoses missed or delayed.^{15,16,20,21} Screening and early diagnosis may reduce the risk of morbidity and mortality for people with PAD,²² but a stronger evidence base may be needed for health policy change and coverage. What must and can be achieved now is elevated awareness.

PAD prevalence in the U.S. is on track to **triple in the next 30 years**



— unless we work to prevent it. —

RIGHT NOW, WE HAVE AN OPPORTUNITY

This Action Plan will be used to guide a collaborative and enduring road map to prevent PAD, reduce its most serious complications and improve quality of life for people living with this disease.

THE SIX GOALS

of the National Action Plan

1

Reach people with PAD and those at risk for PAD by **improving public awareness** of PAD symptoms and diagnosis.

2

Enhance professional education for multidisciplinary health care professionals who care for people with PAD.

3

Activate health care systems to provide enhanced programs for the **detection and treatment** of PAD patients, with a focus on understanding and addressing patient-centered **outcomes**.

4

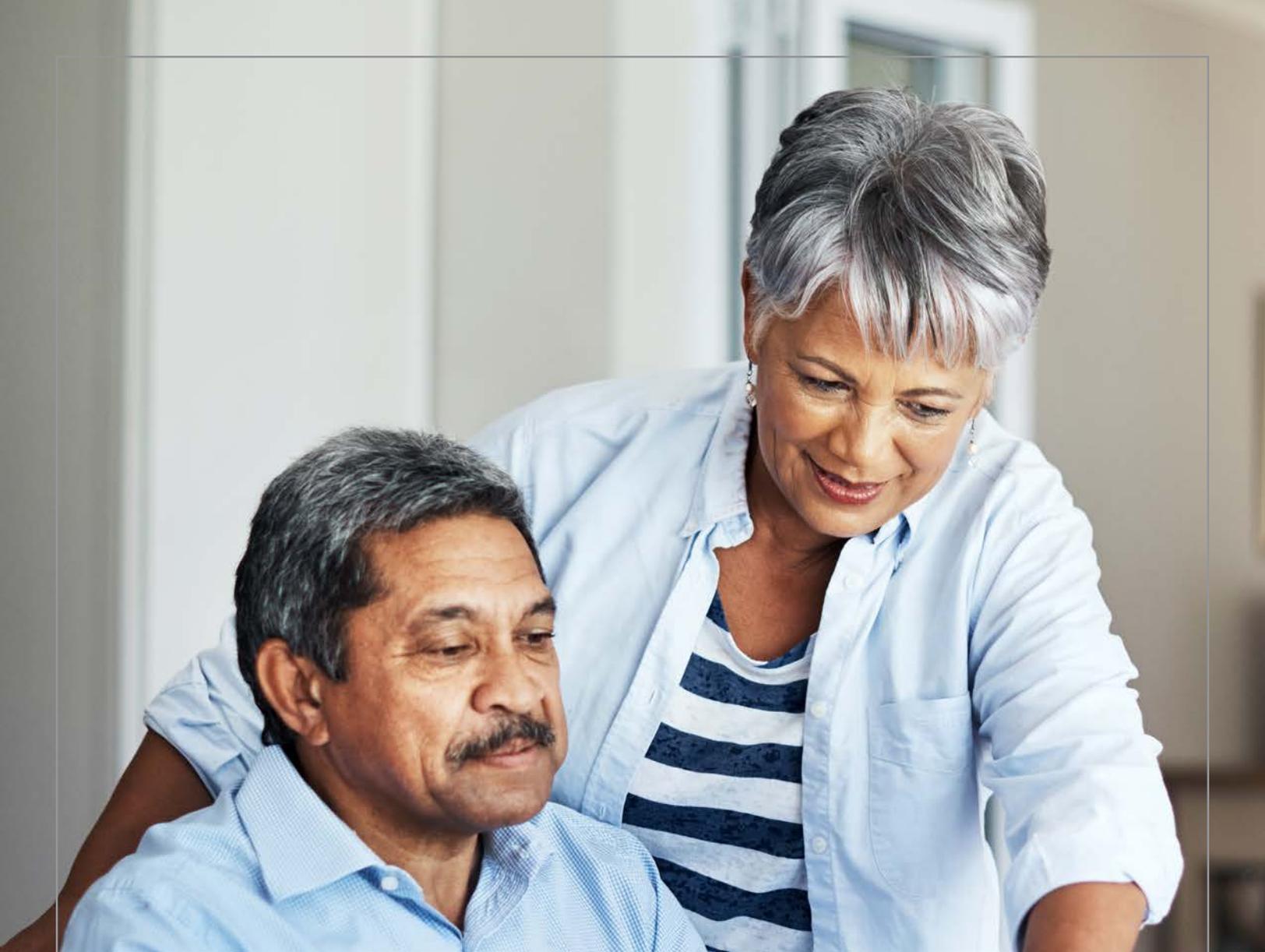
Reduce the rates of nontraumatic lower extremity amputations related to PAD through public outcome reporting and **public health interventions**.

5

Increase and sustain **research** to better understand prevention, diagnosis and treatment of PAD.

6

Coordinate PAD **advocacy** efforts to shape national policy and improve health outcomes.



GOAL 1: PUBLIC AWARENESS

Reach people with PAD and those at risk for PAD by **improving public awareness** of PAD symptoms and diagnosis.

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GOAL 1



Despite its high prevalence in older adults and potentially severe impact on health outcomes and quality of life, national awareness of PAD is low, even among some health care professionals. Furthermore, some patients with PAD never become aware of their disease, attributing their leg symptoms incorrectly to “slowing down” with age. In the most tragic example of this phenomenon, some patients do not become aware of PAD until they are diagnosed with severe limb-threatening PAD, and the first treatment they are offered is amputation. Increased awareness of PAD has the potential to alter disease prognosis through early institution of therapies that are known to reduce the risk of adverse cardiovascular and limb events in patients with PAD.²³⁻²⁵

Compounding these issues, low PAD awareness in communities of underrepresented races and ethnicities coincides with excess risk. PAD disproportionately affects Black Americans, with a prevalence of 15.6% among African American Medicare beneficiaries compared with 11.4% of White Medicare beneficiaries.⁶ Although African Americans suffer disproportionately from PAD and its associated outcomes and comorbidities, they are less likely to be aware of PAD.² Hispanic patients have lower rates of PAD than both Black and White patients, but they tend to have worse outcomes than White patients.²⁶⁻³¹ Hispanics comprise a growing segment of the total U.S. population, and their

awareness of PAD is also low. A cross-sectional telephone survey conducted in 2006¹⁹ that oversampled African American and Hispanic patients found that only 26% of respondents were familiar with PAD compared with higher awareness of other cardiovascular disease conditions.¹⁹ A decade later, awareness of PAD remains poor. In surveys the American Heart Association conducted in 2017-18, groups with connections to the AHA, like Go Red for Women participants, were more likely to have heard of PAD, but focus groups among African American and Hispanic senior communities in Chicago in 2018 showed that only 21% of participants had heard of PAD.³²

GOAL 1

Awareness of the symptoms of PAD is similarly poor. Only a third of African American and Hispanic participants in focus groups conducted by the AHA were aware that leg pain with walking might be a symptom of PAD. One participant had a parent with amputation but was unaware that vascular disease may lead to amputation.³²

Given the high stakes — the amputation epidemic among Black Americans, a growing population of Hispanic Americans with disproportionately poor outcomes, and health disparities regarding treatment of PAD leading to poorer outcomes among patients of underrepresented races and ethnicities — it is essential that we identify appropriate messaging around PAD and the means for disseminating it most effectively in a widespread fashion to the highest-risk groups.



ACTION 1.1:

Establish a diverse national patient advisory group to identify what information needs to be communicated to address public awareness gaps and how best to communicate it.

RATIONALE

Patient advisory groups (PAG) play a key role in improving clinical performance and advancing patient-centered care.³³ These groups empower patients to provide insights into their experiences of illness and the health care system, with the goal of helping health care professionals design more effective patient care.³³ A PAG is key to several areas of the Action Plan. In goal 1, this group will play a key role in developing and refining the messaging to provide valuable input into what the public needs to know about PAD and how best to convey that information. The patient advisory group will reflect the importance of addressing health disparities in PAD, wherein health disparities are preventable differences in health outcomes among groups, often defined by race, ethnicity, sex, education or socioeconomic status as well as geographic location.² Once potential message concepts are developed, focus groups of patients, families, people at high risk for PAD, health care professionals and other priority audiences can be convened to test the concepts' relevance and effectiveness. This will also provide an opportunity to learn more about individual attitudes and beliefs as well as what type of messaging is most effective. Patients also can be ideal spokespeople and focal points for community outreach, sharing their lived experience of PAD with their communities and the public at large.

GOAL 1

Because the PAG will be involved in identifying resonant and high-impact messaging, including the mode of transmission of messaging (for example in-person education, webinars, videos, illustrations and written materials), it will be important to have a communications expert as part of the PAG. Similarly, the PAG should have guidance from a clinician who is an expert in the diagnosis and treatment of PAD. Community health workers and community leaders also should be represented since these individuals are important in disseminating information about PAD.

TACTICS

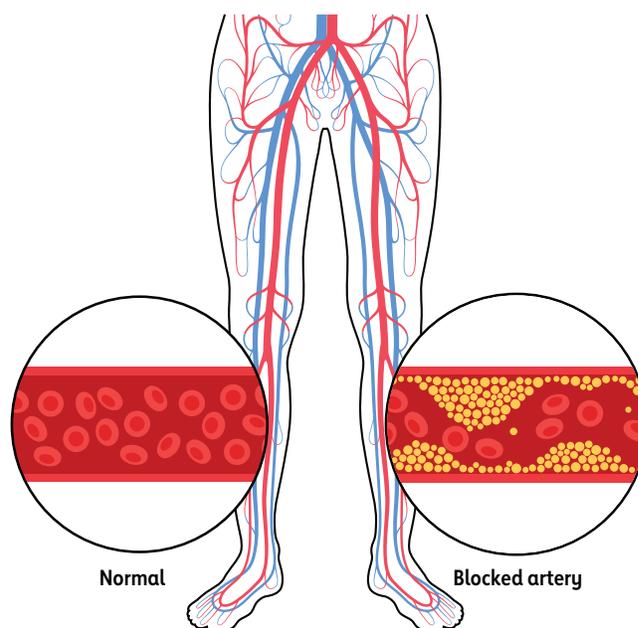
- 1.1A** Identify 12 PAG members who agree to participate for two years and hold regular meetings, initially monthly. Diverse members will be identified with respect to age, sex, race, ethnicity and U.S. region. This PAG will also include a communications expert.
- 1.1B** Receive written feedback from the PAG on elements of PAD messaging and strategies to reach high-risk populations.
- 1.1C** Develop one community outreach opportunity for each PAG member to increase awareness of PAD.
- 1.1D** After their first year of participation, PAG members will cultivate a mentoring relationship with a potential new member to help foster and sustain the group.

ACTION 1.2:

Develop messaging to increase awareness of PAD for diverse priority audiences within the general population.

RATIONALE

Low public awareness of PAD may be due to many factors. The hypothesized reasons for this are likely multifactorial. The term “peripheral artery disease” is difficult to spell and pronounce, and its meaning is not inherently



obvious. The term “peripheral” may also minimize the importance of PAD to patients. The acronym PAD requires explanation. Poor provider awareness almost certainly leads to less education about PAD in the primary care clinic, and thus lower awareness.²¹ Finally, patients may have heard multiple terms for PAD, such as “poor circulation,” “blood clots” and “leg blockages,” among others, but may not be aware that these terms all describe the same phenomenon.

GOAL 1

To surmount these difficulties, it is critical to develop clear, concise, consistent language that PAD patients, people at risk for PAD and the public can understand. The language must allow for differences in health literacy and should be translatable into other languages, particularly Spanish.

TACTICS

- 1.2A** Develop a clear, effective phrase to indicate PAD that can be used for outreach to patients, communities and health care professionals (e.g., leg attack, leg amputation disease, leg angina and blocked leg arteries).
- 1.2B** Create messaging tailored for diverse priority groups, such as those with cardiovascular disease or diabetes or who use tobacco and communities with high prevalence of PAD, including Black and Native American people as well as people in under-resourced areas.
- 1.2C** Test messaging with focus groups or online discussion boards in geographic areas with diverse high-risk populations.
- 1.2D** Identify effective messaging for those with PAD, including risk for various outcomes, best disease management practices, support groups and the heart-brain-leg connection.

ACTION 1.3: Prioritize the approach to reach at-risk groups for messaging.

RATIONALE

Because funding for public health campaigns is very limited and communicating with the public on a large scale can be expensive, it is important to make sure that PAD messaging is sustainable and reaches the people who are most likely to benefit. PAD messaging delivered to the general public is less likely to be effective than messaging to specific groups. Nevertheless, effective messaging rolled out to priority populations may help raise the level of PAD knowledge for other groups as well.

Strongest risk factors for PAD



diabetes



smoking

Patients with both are at the highest risk for PAD morbidity & mortality

The two strongest risk factors for PAD are diabetes and smoking, and patients with both risk factors are at the highest risk for PAD morbidity and mortality, including limb loss.⁴ Patients with dyslipidemia and hypertension are also at high risk. Messaging designed to reach populations with high rates of diabetes and smoking and those with other risk factors

GOAL 1

may motivate more behavior change because these people have more at stake and the problem has more perceived urgency. Similarly, because of the disproportionate impact of PAD on Black, Hispanic and Native American people as well as people in under-resourced areas, messaging directly to these groups is likely to have a greater overall benefit.

TACTICS

- 1.3A** Conduct a literature review to identify populations at high risk for PAD, including nontraditional groups.
- 1.3B** Create a PAD map of the country based on prevalence of amputation, diabetes, smoking and known PAD to highlight priority regions for more intensive outreach.
- 1.3C** Develop collaborations with individuals already working to reduce health disparities, such as community health workers who have the greatest access to persons at risk.
- 1.3D** Partner with communities for outreach opportunities, such as neighborhood health fairs, faith-based gatherings and engagement of families through social safety net organizations.
- 1.3E** Increase involvement in current programs focused on diabetes, tobacco use, hypertension control and heart/stroke risk.

ACTION 1.4: Identify partners to amplify consumer awareness initiatives.

RATIONALE

Casting a wide net for partners allows for reaching the largest possible number of people at risk but doing so may be time-consuming and labor-intensive. The most effective strategy for finding strong partners will be to identify programs that are already doing health education work for people at risk of PAD and related health issues.

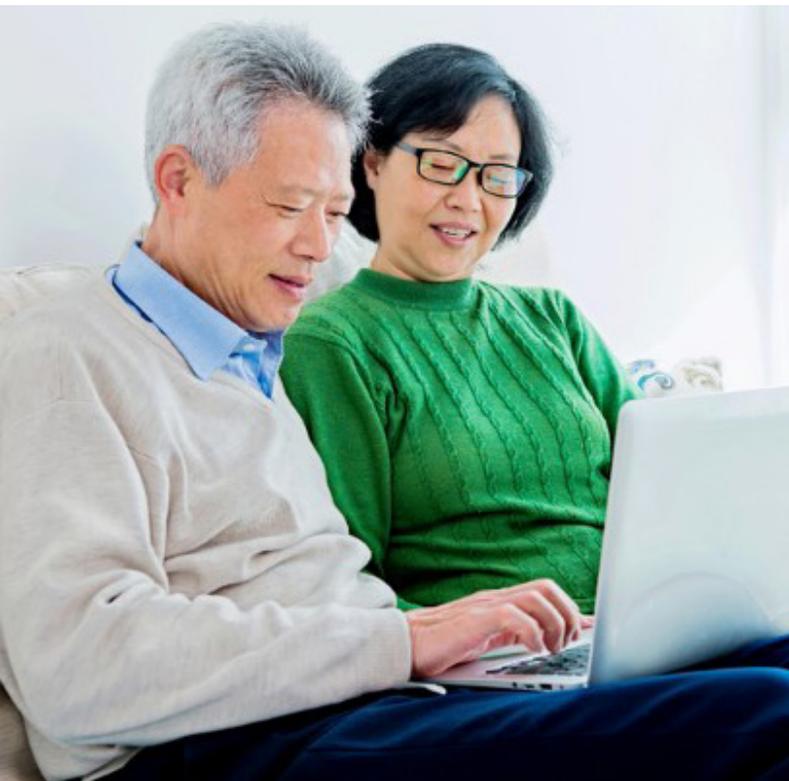
One of the potential difficulties with public health messages is that even though patients have heard them, messaging alone may not spur them to action. Awareness and information are necessary, but not usually sufficient, to motivate behavior change. Several studies have shown that community-based interventions may increase the likelihood of patients' acting on messaging. Organizations of community health workers and other allied community health care professionals, who often live in the communities they serve, will be critical partners in helping disseminate PAD messages and ensuring that at-risk patients and those with PAD reach medical services.

Furthermore, because the risk factors for PAD, coronary artery disease and cerebrovascular disease are similar, and because diabetes is often a common thread among the three, collaboration with organizations already working with these patient populations will allow for integrating PAD into messaging about these related conditions.

GOAL 1

TACTICS

- 1.4A** Develop a roster of collaborating organizations that have pledged commitment to the PAD National Action Plan.
- 1.4B** Establish a strategy and timeline for consumer outreach (key messaging, graphics, web-based and community efforts).
- 1.4C** Foster local collaborations for community awareness focusing on areas with racial and socioeconomic disparities (e.g., the National Association of Community Health Workers and the National Association of Community Health Centers).



ACTION 1.5: Secure funding to launch and sustain PAD consumer awareness initiatives.

RATIONALE

Some communication with people at risk for PAD, people with PAD, their families and their caregivers can be accomplished at the grassroots level with modest resources, but widespread communication with consistent messaging on a national scale requires significant funding. To ensure a coordinated national approach to raising awareness of PAD and its risk factors and symptoms, large-scale funding from nonprofit and corporate sources will be needed.

Messaging is likely to be more expensive on the front end as communication strategies are developed and fine-tuned. When messaging is clear and relevant, it is more likely to be effective — and more likely to be sustainable. In other words, when messaging permeates the consciousness of a population and becomes part of the culture, it is less expensive to maintain.

TACTICS

- 1.5A** Leveraging relationships from key stakeholders (nonprofit and industry) to host webinars for possible funders to discuss opportunities.
- 1.5B** Identify and pursue options for earned media/media coverage as well as in-kind airtime on radio or television spots and space on social media.



GOAL 2: PROFESSIONAL EDUCATION

Enhance professional education for multidisciplinary health care professionals who care for people with PAD.

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GOAL 2



Patients with PAD may present to professionals ranging from primary care clinicians to endocrinologists, cardiologists, vascular specialists, podiatrists and others. Providing additional education about current best practices for PAD detection and care is a key approach to advance PAD care in an equitable fashion. Professional education about PAD must be improved so these varied practitioners can be well equipped to advocate for patients and provide them with optimal medical and behavioral therapies to improve their quality of life and prevent severe consequences. Behavioral and lifestyle changes are critical to combating the daily challenges of living with PAD. However, many clinicians lack the knowledge needed to empower patients to implement and sustain these changes.

A unified, multidisciplinary educational curriculum should be developed and disseminated across disciplines, and standardized vascular content should be incorporated into certifications, so that physicians (including podiatrists), nurses, advanced practice providers, nutritionists, vascular technologists and other allied health care professionals have a shared baseline understanding of PAD. In addition, computerized decision support for PAD could be incorporated into existing systems so that multidisciplinary professionals can effectively diagnose patients and provide optimal care. Early PAD recognition can help prevent disease progression and prevent severe life- and limb-threatening outcomes.

ACTION 2.1:
Teach professionals how to empower patients with PAD to make and sustain self-care strategies.

RATIONALE

The multiple health care professionals who care for PAD patients and those at risk for PAD need a solid, shared foundation of knowledge about current best practices in the field. There are currently effective pharmacologic and behavioral interventions that will improve outcomes and quality of life for patients with PAD. However, motivating patients to initiate and sustain lifestyle changes can be difficult.

GOAL 2

Patients need to be motivated and empowered to make sustainable lifestyle changes. Clinicians need effective, evidence-based tools and strategies to help patients initiate healthy behaviors and sustain them over the long term. Additional training, tailored to different kinds of health care professionals, must be provided to clinicians through existing mechanisms such as pre-service training and CME. Interprofessional collaboration is essential to empower patients to take responsibility for self-care and improve outcomes and quality of life.

TACTICS

- 2.1A** Engage established patient advisory groups (see Goal 1) to capture patient perspectives on empowerment needs.
- 2.1B** Create training opportunities for health care professionals to improve patient empowerment skills.
- 2.1C** Incorporate PAD into existing self-care apps, such as Corrie, FAITH or a walking podcast/app to guide home-based walking.
- 2.1D** Conduct clinician and allied professional focus groups to identify and target specific educational needs.

ACTION 2.2: Develop and disseminate educational curriculum to multidisciplinary health care professionals.

RATIONALE

Different categories of health care professionals — physicians (including podiatrists), nurses, advanced practice providers, nutritionists, vascular technologists, clinical exercise physiologists and others — need different levels of understanding to facilitate care of a PAD patient.

Health care professionals who facilitate care of PAD patients



physicians



nurses



advanced
practice
providers



clinical
exercise
physiologists



nutritionists



vascular
technologists

Increasing awareness of PAD among frontline clinicians and allied professionals of multiple disciplines can increase early diagnosis and treatment, which can be expected to improve patient symptoms, reduce cardiovascular risk and limb events, improve the quality of life³⁴ and potentially reduce costs.³⁵

A unified, multidisciplinary educational curriculum is needed for health care professionals. A challenge may be

GOAL 2

harmonization of clinical practice guidelines (see tactic 2.2A). Nonetheless, creation of a centralized, curated and up-to-date repository of professional educational materials from various trusted sources is readily achievable and will increase provider access and knowledge across the continuum of care and enable quality, evidence-based treatment in line with best practices. Opportunities should be identified to actively disseminate these educational materials across disciplines.

TACTICS

- 2.2A** Create a repository of professional education materials organized by topic, source, media format and audience (e.g., primary care, podiatry and rehabilitation) with ongoing curation.
- 2.2B** Develop a virtual PAD professional education program for frontline primary care clinicians with a pre- and post-professional knowledge survey.

- 2.2C** Petition the Accreditation Council for Graduate Medical Education to include PAD detection and management in program requirements for medical students, family medicine, and internal medicine training.
- 2.2D** Petition American Nurses Credentialing Center, American Association of Nurse Practitioners and American Academy of Physician Assistants to add vascular content to training requirements.
- 2.2E** Develop a PAD certificate of training through an appropriate collaborative group.
- 2.2F** Create a vascular speakers bureau of experts who conduct virtual or in-person presentations.



GOAL 2

ACTION 2.3: Promote and disseminate PAD guidelines to multidisciplinary health care professionals.

RATIONALE

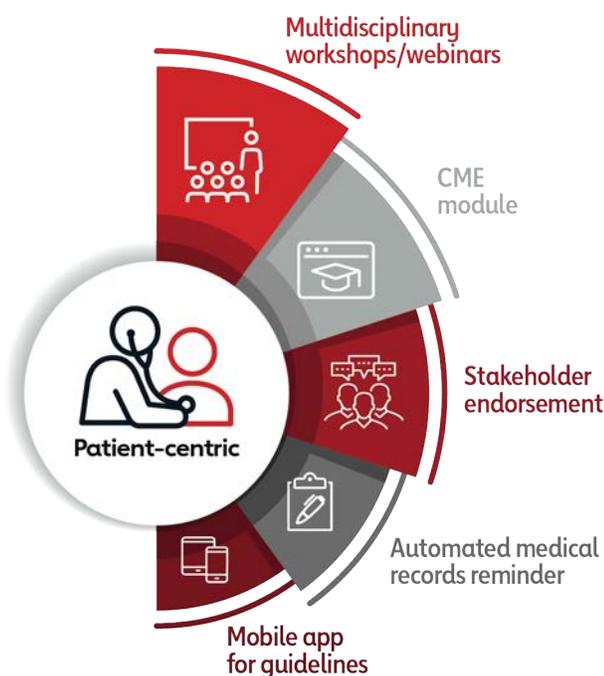
Since 1980, the American College of Cardiology (ACC), the United States Preventive Services Task Force (USPSTF) and the American Heart Association (AHA) have translated scientific evidence into clinical practice guidelines with recommendations to improve cardiovascular health. These guidelines, which are based on systematic methods to evaluate and classify evidence, provide a foundation for the delivery of quality cardiovascular care. The ACC and AHA sponsor the development and publication of clinical practice guidelines without commercial support, and members volunteer their time to the writing and review efforts.

In addition, other professional society guidelines exist for the diagnosis, treatment and management of patients with PAD. Thus, a large amount of evidence-based research is available to guide the diagnosis, medical management, prevention and treatment of PAD. However, broad dissemination and uptake of existing guidelines remains a challenge.

To address this challenge, the guidelines must be consistent, multidisciplinary and patient-centric, and they must be integrated with existing electronic medical record tools. The lower extremity PAD guidelines, including a clinical decision tree and other tools, should be effectively disseminated and be accessible and easy to use for all levels of clinicians.

TACTICS

- 2.3A** Hold multidisciplinary workshops/webinars to discuss areas of concordance in PAD guidelines from multiple specialty groups, including professional societies, governmental agencies and patient advocacy groups.
- 2.3B** Develop a PAD guidelines CME module endorsed by stakeholder organizations to educate clinicians.
- 2.3C** Develop, implement and evaluate an automated electronic medical record PAD guideline reminder in a single hospital or health system to provide pilot data for others who may be interested in adoption.
- 2.3D** Develop an app for PAD guidelines to facilitate guideline-directed care at the point of care.



GOAL 2

ACTION 2.4: Increase awareness, detection and screening of patients at risk for PAD through provider engagement.

RATIONALE

In addition to the severe outcomes associated with PAD, the condition is a marker for systemic atherosclerotic disease and is associated with increased risk of illness and death from coronary and cerebrovascular disease.^{36,37} Thus, diagnosis of PAD also can lead to the early detection and treatment of coronary artery disease and cerebrovascular disease as well as preventing limb loss. However, despite evidence, patients with PAD receive suboptimal risk modification strategies.^{21,38}

TACTICS

- 2.4A** Educate multidisciplinary clinicians about identifying and evaluating patients at high risk for PAD.
- 2.4B** Set three goals for clinicians: 1) recognize that PAD increases the risk of coronary artery disease and cardiovascular disease; 2) recognize PAD (take shoes and socks off); and 3) treat PAD (guideline-directed medical therapy) and provide treatment for leg symptoms.
- 2.4C** Develop, implement and evaluate a point of care based tool for clinicians to implement guideline-based care for patients.



ACTION 2.5: Provide practice support and improve patient access to guideline-directed medical care.

RATIONALE

Computerized decision support has been shown to overcome knowledge gaps and optimize guideline-based care.³⁹ Successes in alert-based computerized decision support include prevention of venous thromboembolism in high-risk hospitalized patients⁴⁰ and, more recently, prevention of stroke in patients with atrial fibrillation.⁴¹

Many aspects of PAD care, from diagnosis to optimal treatment, are well suited to a computerized decision support approach to multidisciplinary care. First, excellent and

GOAL 2

up-to-date evidence-based guidelines for PAD care exist and can easily be integrated into an alert-based computerized decision support program. Second, several therapeutic options exist (supervised exercise programs, hybrid antithrombotic-antiplatelet regimens, intensive lipid lowering with PCSK9 inhibitors, etc.) and can be included into an actionable PAD care template. Other key areas of clinical need include support for smoking cessation. Such a template can be linked to the evidence base for self-directed learning within the architecture of the computerized decision support software.

TACTICS

- 2.5A** Identify geographically remote and under-resourced settings where a computerized decision support model may offer the most practice support.
- 2.5B** Identify professional societies/specialty organizations to partner in development of the computerized decision support model.
- 2.5C** Hold multidisciplinary workshops/webinars to create a computerized decision support model in partnership with professional/specialty groups.
- 2.5D** Implement and evaluate the decision support tool and test within a single hospital or health system to provide pilot data for others who may be interested in adoption.





GOAL 3: DETECTION & TREATMENT

Activate health care systems to provide enhanced programs for the **detection and treatment** of PAD patients, with a focus on understanding and addressing patient-centered **outcomes**.

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A quality-of-care program with an emphasis on structure, processes and outcomes can be an effective framework for activating health care systems to optimize care. For PAD care, an activation framework would have a multidisciplinary focus and be characterized by patient-engaged design and governance. This approach to activation of health care systems can engage clinicians across the care continuum, including primary, secondary and tertiary care.

Health care systems are defined broadly here and include: independently governed care delivery units, such as practices delivering outpatient services; larger health care systems; and teaching, non-teaching, academic and non-academic hospitals that deliver inpatient as well as outpatient care.

The actions described here have a central focus on formally tracking outcomes. Immediate focus areas for quality-of-care improvement include: a) detection of PAD; b) medical management standards; c) patient-centered care; and d) quality standards for supervised exercise therapy programs/networks. The ideal long-term outcome would be an accreditation program for comprehensive PAD care centers, with a joint commission and underwriting of different professional organizations.

Immediate focus areas for quality-of-care improvement



detection of PAD



medical management standards



patient-centered care



quality standards for supervised exercise therapy programs/networks

GOAL 3

ACTION 3.1: Improve PAD detection, treatment and timely referral for revascularization through health system activation.

RATIONALE

Despite PAD's high incidence and prevalence in the United States, PAD awareness is low among health care professionals and the public, and it frequently goes undetected and undertreated. The PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) study demonstrated that despite the significant prevalence of PAD among primary care patients in the U.S., PAD was underdiagnosed by clinicians and undertreated compared with other atherosclerotic cardiovascular diseases.²¹ In addition, racial and ethnic inequities in PAD prevention, detection and treatment must be addressed.

Earlier detection can allow better treatment and prevention of the most severe outcomes of PAD, such as amputation. A population screening and intervention trial in Danish men, the Viborg Vascular trial, demonstrated that triple screening for abdominal aortic aneurysm, PAD and hypertension reduced overall mortality through improved identification and treatment.⁴² Lipid lowering and antithrombotic therapies reduce the risk of adverse cardiovascular and limb events in patients with PAD.^{21,42,43} Timely referral to revascularization is critical for limb preservation if noninvasive therapies fail.

TACTICS

- 3.1A** Develop a system-wide health care PAD detection and treatment surveillance program, including a mechanism for reporting relevant data. This would include:
- Number of PAD cases detected
 - Patient factors
 - Outcomes (amputations and hospitalizations for acute limb ischemia)
 - Blood pressure control, antithrombotic therapy and lipid lowering utilization
 - Smoking status
 - Clinician/health system factors
 - Use of multidisciplinary teams
 - Use of shared decision-making approach
 - Referral to cognitive behavioral therapy
 - Screening for behavioral risk factors
- 3.1B** Pilot the PAD detection and treatment surveillance program in a single health system to provide formative evaluation data that support broader adoption.
- 3.1C** Promote health system utilization of these systemwide PAD detection and treatment surveillance programs through national quality-of-care programs.

GOAL 3

ACTION 3.2: Develop approaches for patient-centered PAD care.

RATIONALE

PAD has profound implications for patients with respect to their overall health status and quality of life.^{43,44} Besides cardiovascular risk management, treatment goals of PAD include symptom relief, improved functioning and improved quality of life. Current treatments for PAD symptom relief include supervised exercise therapy, medications, and endovascular and surgical revascularization.⁴⁵

In patient-centered care, the patients' needs and desired outcomes are the basis for clinical decision-making. Care is measurement-based to ensure quality of care, and decision-making is shared among patients, their families and their care team.⁴⁶ As care for PAD is provided by a broad range of health care providers, partners of patient-centered care design should reflect the diversity in specialties, including, but not limited to, vascular surgery, both interventional and non-interventional cardiology, interventional radiology, vascular medicine, primary care providers, podiatry, nutritional health, behavioral health and physical therapy.

Effective patient-centered care approaches for PAD offered by health systems should focus on a) measurement-based care to ensure quality of care, including quality metrics that capture the patients' perspective; b) seeking ways to engage patients in conversations and partnerships that review evidence-based treatment options in line with patients' preferences; and c) providing holistic PAD care that recognizes the multidisciplinary care needs of the PAD patient population.

TACTICS

- 3.2A** Develop, implement and evaluate a patient-reported outcomes tool in clinical settings, including screening for mental health risk and, when developed, incorporate into surveillance systems established in Action 3.1 (see page 23).
- 3.2B** Pilot shared decision-making models in diverse settings, such as podiatry, vascular surgery, vascular medicine and primary care.
- 3.2C** Develop and deploy a clinician education module on shared decision-making approaches for PAD care.
- 3.2D** Develop, implement and evaluate a framework for a psychoeducation program, including core elements.



GOAL 3

ACTION 3.3: Establish standards and accreditation for supervised exercise therapy programs.

RATIONALE

Supervised exercise therapy (SET) is a low-cost, effective, validated and low-risk intervention for people living with PAD and intermittent claudication (IC). However, SET is an underutilized and under-recognized therapeutic approach that is not universally available, even at centers that already provide cardiac rehabilitation.

Supervised exercise therapy is a Class 1A recommendation for patients with IC to reduce symptoms and improve functional status and quality of life.⁴⁵ In 2017, the Centers for Medicare & Medicaid Services issued a national coverage determination to cover SET for beneficiaries with IC to treat symptomatic PAD.⁵¹ Medicare

will cover up to 36 sessions over a 12-week period if all of the following components of a SET program are met: a) sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication; b) conducted in a hospital outpatient setting or a physician's office; c) delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD.

Despite the coverage determination and strong evidence for SET's effectiveness, implementation gaps remain.⁴⁷ This provides a significant opportunity to integrate SET into patient-centered clinical and systems approaches to comprehensive cardiovascular risk reduction, including to prevent PAD and reduce symptoms in patient with diagnosed PAD. Importantly, evidence is needed to support SET as a component of a multidisciplinary strategy (aligned with cardiac rehabilitation) to improve vascular outcomes.

TACTICS

- 3.3A** Develop a standardized national SET curriculum for cardiovascular rehabilitation staff and physical therapy professionals.
- 3.3B** Create a comprehensive communication strategy to increase clinicians' awareness of SET and provide information on indications for referral and how to refer.
- 3.3C** Develop a registry to collect functional status outcomes and quality metrics for the delivery of SET.





GOAL 4: PUBLIC HEALTH

Reduce the rates of nontraumatic lower extremity amputations related to PAD through public outcome reporting and **public health interventions.**

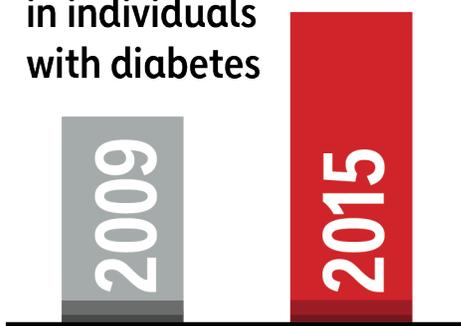
Leads: J. Antonio Gutierrez, MD, MHS and Kunihiro Matsushita, MD, PhD

Group Members: Josh A. Beckman, MD; Yazan Duwayri, MD, MBA; Aaron Horne, Jr., MD, MHS; Scott Kinlay, MBBS PhD; Dyane E. Tower, DPM, MPH; Christopher J. White, MD; Linda Amos; Barbara Entl, MD



Amputation of a leg or foot is a devastating consequence of PAD, with considerable impact on the quality of life for patients and their families. A recent report indicated an increase by 50% of nontraumatic lower extremity amputations in individuals with diabetes between 2009 and 2015.¹¹ Though amputation may be required in some patients, in many cases it can be prevented with timely diagnosis and treatment of limb ischemia. Achieving the goal of reducing amputation calls for better data collection, new models for payment and care, improved public policy, and awareness raising among expert organizations, government agencies and the media.

50% increase
of nontraumatic lower
extremity amputations
in individuals
with diabetes



A key factor is the lack of outcomes data, which are needed so that resources can be targeted effectively. For example, data on amputations from administrative and billing databases generally do not distinguish between PAD-related amputations and those due to other indications, such as trauma. These claims-based data are subject to billing practices and therefore may overestimate or underestimate some outcomes.⁶

Another factor hampering efforts to reduce PAD-related amputations is the lack of a payment and service delivery model to support best-practice care for patients. Such a model could support identifying patients at risk of

GOAL 4

PAD, promoting medical and exercise therapy to prevent progression, and regularly evaluating lower extremities for those diagnosed with PAD.⁴⁸ In addition, recommendations for using ankle-brachial index (ABI) to evaluate people at high risk remain variable across states.⁴⁹ A standard public policy for PAD screening is needed to ensure both geographical and financial access to early detection.

Lack of awareness of PAD is another barrier to reducing amputation rates. This low awareness extends beyond the public and health care professionals as noted in previous sections. The impact of PAD, especially its relationship to amputation, is also underappreciated by many expert organizations, government organizations and the media. For example, the 2014 Surgeon General's report on smoking does not even mention amputation in relation to PAD.⁵⁰ Increasing awareness among these groups is essential to improving early detection and treatment enabling PAD patients to avoid amputation.



ACTION 4.1: Establish system for public reporting of amputations at the hospital level.

RATIONALE

Major amputations impede a patient's quality of life and day-to-day function. Although some major amputations for PAD are inevitable due to unsalvageable tissue loss or infection, many may be avoidable through timely revascularization and wound care and early detection and treatment of PAD. Therefore, data on avoidable major amputations and attempts to salvage the limb by revascularization are critical to understanding the extent of the problem and reducing major amputations.

Minor amputations (below the ankle) tend to cause less impairment of walking function, but understanding patterns of minor amputation may help provide a more complete picture of limb salvage attempts. For example, centers with higher ratios of minor to major amputations accompanied by revascularization may reflect greater attempts at limb salvage.

The current knowledge about the prevalence and indications of lower extremity amputations relies on administrative and billing databases. These sources lack detail about the specific indications (e.g., PAD versus trauma), previous limb salvage attempts and patient factors. Since most patients with critical limb ischemia or amputation are managed in a hospital, institutional data could better inform reporting of regional and nationwide trends.

GOAL 4

TACTICS

- 4.1A** Develop data collection standards for nationwide reporting of amputations through publication of a multistakeholder scientific statement.
- 4.1B** Optimize potential models for reporting of amputation data and achieve consensus across key stakeholders.
- 4.1C** Pilot the amputation reporting model in a single or multiple statewide system(s) to assess validity and provide formative evaluation data that support broader adoption.
- 4.1D** Conduct focus groups among stakeholders and policymakers to assess program acceptability.
- 4.1E** Promote utilization of a nationwide amputation reporting system.

ACTION 4.2: Develop and implement public policy for payment and service delivery model to improve PAD care.

RATIONALE

Complications associated with PAD, including amputation, are detrimental to patients and costly for the health care delivery system. Complications may be prevented if risk factors are detected and addressed early in the progression of PAD. To deliver timely, quality PAD care, there must be a delivery and payment mechanism to support the best treatment and preventive care possible for patients, especially those at highest risk including patients with diabetes or prior peripheral revascularization or amputations.⁴⁸

The service delivery and payment mechanism will improve the timely identification and subsequent management of PAD for patients. Furthermore, public awareness, provider education and prevention strategies could reduce hospitalizations, thereby improving patient quality of life and minimizing expenditures.

TACTICS

- 4.2A** Develop payment models to reduce nontraumatic amputation rates by promoting preventive care of PAD.
- 4.2B** Assess acceptability, adoptability and sustainability through pilot testing and multidisciplinary stakeholder workshops.



GOAL 4

ACTION 4.3: **Establish policy priorities for PAD detection in people at high risk for amputation.**

RATIONALE

Despite its prevalence and adverse impacts on patients, PAD is often underappreciated and underdiagnosed.⁵¹ When patients do not report typical leg symptoms, clinicians are less likely to suspect PAD, further diminishing opportunities for timely diagnosis.⁵² Moreover, the majority of patients with PAD have complicated symptoms, each of which are associated with limb function decline.⁵³ Screening for PAD in high-risk people provides the only reliable way to improve diagnosis and treatment.

Although professional societies and national U.S. health care organizations recommend screening for PAD using the ABI, the U.S. Preventive Services Task Force recently concluded that the evidence for PAD screening with ABI is insufficient.⁵⁴ As a result, screening

remains unavailable to many patients at high risk. Even obtaining an ABI as a diagnostic test can be difficult, since financial coverage of the ABI test varies by state.⁴⁹ This is a critical gap: early detection of PAD is essential for optimizing its management to prevent lower extremity amputations and reduce heart attack, stroke and death.

TACTICS

- 4.3A** Develop policy priorities for PAD detection through a collaborative, multidisciplinary working group of expert clinicians along with government and health care organizations.
- 4.3B** Pilot a PAD detection program in people at high risk for amputation to assess its acceptability and sustainability.
- 4.3C** Present scientific data to support coverage for PAD detection in high-risk people.



GOAL 4

ACTION 4.4: Urge expert organizations, government agencies, public organizations and the media to highlight amputation.

RATIONALE

PAD is often underappreciated by both clinicians and patients, which contributes to the lack of awareness of PAD in the community and the underrepresentation of PAD in government-directed health initiatives.¹⁹ In particular, the potential for severe, life-altering complications, such as amputation, is underappreciated.⁵⁵

For example, the 2014 Surgeon General's report on smoking describes PAD alongside other cardiovascular diseases associated with smoking but does not mention amputation.⁵⁰ The "Heart Disease" section of the Centers for Disease Control and Prevention's website lists PAD under "other conditions related to heart disease" and does not mention amputation.⁵⁶ These examples underscore the need to further advocate for recognition of PAD and its most severe complication — lower extremity amputation — to expert organizations and government agencies.

TACTICS

- 4.4A** Develop collaborations with major national health equity organizations, such as the Allies for Reaching Community Health Equity (ARCHE); Center for Health Equity and Place (CHEP); Racial and Ethnic Approaches to Community Health (REACH); Centers for Excellence for Elimination of Health Disparities (CEED); Indian Health Services (IHS); National Alliance for Hispanic Health; National Collaborative for Health Equity; National Institute on Minority Health and Health Disparities; and the Praxis Project to highlight and publicize the health disparities related to PAD and the consequences of untreated PAD, specifically amputation risk in communities of underrepresented races and ethnicities.
- 4.4B** Collaborate with government agencies and public health organizations to highlight amputation, including proposing a surgeon general's report on lower extremity nontraumatic amputation.
- 4.4C** In collaboration with patient advocacy groups (see Goal 1), share patient stories in the media about risk of amputation for diverse ethnic and racial groups.



GOAL 5: RESEARCH

Increase and sustain **research** to better understand prevention, diagnosis and treatment of PAD.

Leads: Peter Henke, MD; Diane Reid, MD; Mary M. McDermott, MD

Group Members: Sue Duval, PhD; Diane Treat-Jacobson, PhD RN; Lyndon Joseph, PhD; David W. Schopfer, MD MAS; Michael Conte, MD; John A. Spertus, MD, MPH; Teresa L. Z. Jones, MD; Susan Ziemann, MD PhD; Cheryl Wilson



A better understanding of basic biologic pathways associated with the pathogenesis, mitigating factors, clinical progression and outcomes of PAD, and chronic limb-threatening ischemia (CLTI) will help identify preventive interventions, improve treatments and increase quality of life. Although scientific investigation of PAD has increased steadily, many fundamental questions about pathogenesis and treatment remain unanswered, and adherence, even to evidence-based recommended treatment, remains suboptimal.^{13,57}

Topics of research to help advance knowledge of PAD and improve outcomes are considered in the information provided in this goal within the broad categories of basic and translational research; clinical research; dissemination and implementation research; data science research; and research training and career development. Greater multidisciplinary collaboration of scientists and clinicians is essential to develop and deliver novel therapies and better care to patients with PAD.

ACTION 5.1: Grow basic and translational research in PAD.

RATIONALE

Basic and translational research will increase fundamental knowledge of atherosclerotic PAD, including mechanisms of disease origin and progression, and responses to treatment. The pathophysiology of PAD and CLTI have unique features compared to atherosclerotic disease in other vascular beds,^{52,58} and further research on those mechanisms could potentially lead to PAD-targeted therapies. Research topics might include identifying factors that contribute to pathogenesis of PAD, such as endothelial dysfunction; hemodynamic abnormalities; mitochondrial damage;

GOAL 5

impaired skeletal muscle biology; peripheral vascular calcification; peripheral neuropathy; local and systemic inflammation; angiogenesis; microvascular reserve; cellular and molecular responses to exercise; and “-omics” of PAD and CLTI (genomics, epigenomics, transcriptomics, proteomics and metabolomics).

Because animal models do not replicate the complexity of human PAD, basic research in PAD may include mechanistic studies in human subjects and use of human tissue as well as development of *in vitro* and *in vivo* experimental models. Basic research is also needed on associated comorbidities and risk factors, such as diabetes, hypertension and tobacco use, that affect pathophysiology of PAD. An example is the accumulation of advanced glycation end products in vessel walls secondary to diabetes, especially in the setting of hypertension and advancing age. Additional areas for study include identifying new pathways/targets for therapies; discovering systemic biomarkers for lower extremity PAD; identifying biologic pathways of disability; enabling better pre-procedural assessment to predict response to conduit artery intervention; understanding the mechanism(s) of benefits from exercise; and providing an expanded knowledge base for personalized medicine for people with PAD.

Mechanisms for these studies could include funding opportunity announcements (FOAs) and notices of special interest (NOSIs) from National Institutes of Health, including the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; and the National Institute on Aging, with a focus on basic and translational research in PAD.

TACTICS

- 5.1A** Convene a transdisciplinary yearly workshop to identify gaps and high-priority research questions.
- 5.1B** Develop an active ongoing network of PAD-focused investigators who will exchange ideas and collaborate on scientific endeavors through virtual meetings.
- 5.1C** Improve preclinical models of PAD and CLTI, in part by developing models that better simulate the chronic progressive nature of PAD.
- 5.1D** Create (or expand on existing) central tissue and data repositories to enable wide sharing of resources.
- 5.1E** Increase PAD-relevant funding opportunities from the National Institutes of Health.



GOAL 5

ACTION 5.2: Grow clinical research in PAD.

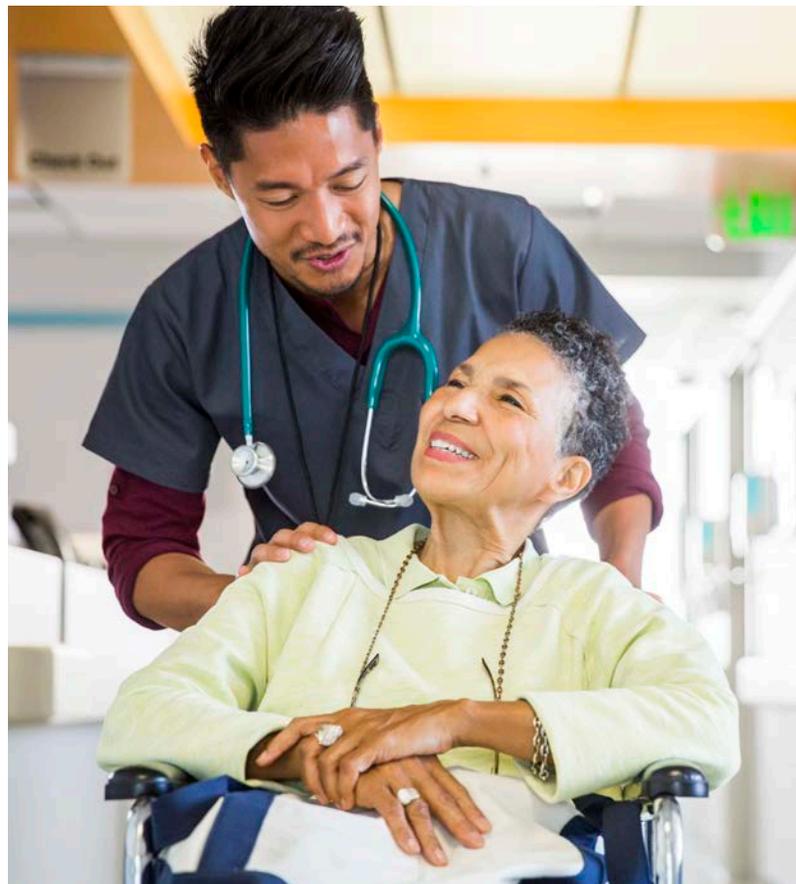
RATIONALE

The American Heart Association and American College of Cardiology clinical practice guidelines have defined optimal medical therapy for patients with PAD.⁴⁵ Improving outcomes for patients with PAD requires clinical research of different types:

- **Clinical trials** to determine the efficacy of potential novel treatments and comparative effectiveness of established treatments to improve PAD outcomes. Clinical trials should include patients previously underrepresented (e.g., women, older adults, and those of diverse racial and ethnic backgrounds) in PAD studies.
- **Observational registries** to understand variation in current treatment practices and associated outcomes while recognizing limitations of observational studies. Population studies may provide insights into incidence and progression of PAD over extended time periods.
- **Implementation and dissemination research**, such as health system-based effectiveness trials to identify best methods for ensuring guideline-recommended physician prescription of optimal medical therapy and high levels of adherence, especially in those patients with limited resources and access to care. Other topics for dissemination and implementation research include appropriate and timely patient referral; participation and adherence to supervised exercise programs; therapies

addressing the biologic, socioeconomic, psychosocial or other barriers to improvement for the 35% of patients with PAD who do not respond to exercise therapy; and effective home-based exercise interventions.^{47,59-63} Community-based dissemination research will be useful in finding ways to increase awareness of PAD, especially in persons at high risk who should consider diagnostic testing.

Patients with PAD represent a diverse group with regard to race, ethnicity and social determinants of health. Research to improve outcomes for patients with PAD should ensure inclusion of diverse populations.



GOAL 5

TACTICS

- 5.2A** Organize a national clinical trials network to enroll patients for PAD-related studies, including underrepresented patients at high risk for adverse outcomes from PAD.
- 5.2B** Urge relevant organizations, such as the National Institutes of Health, American Heart Association, American College of Cardiology, Society for Vascular Medicine, Society for Vascular Surgery and/or Society for Interventional Radiology to sponsor a workshop(s) to prioritize and support clinical research to identify therapies for PAD.
- 5.2C** Enhance participation and collaboration in observational studies and clinical trials within the Vascular Quality Initiative registry.
- 5.2D** Increase specific funding opportunities for clinical research in PAD, including clinical trials and dissemination and implementation research.
- 5.2E** Work with government agencies to understand existing opportunities for PAD research, especially those addressing structural racism.

ACTION 5.3: Grow research training and career development in PAD.

RATIONALE

A critical mass of scientists and trainees is necessary to move any field of medical research forward. Despite the considerable public health impact of PAD, its increasing global prevalence and significant outcome disparities associated with race and social determinants of health, the pace of PAD research has lagged well behind that of other cardiovascular diseases such as coronary artery disease. An accelerated research agenda is paramount to address the many existing gaps in knowledge of PAD including how the pathogenesis of atherosclerosis in lower extremities differs from atherosclerosis in other vascular beds.^{64,65}



GOAL 5

TACTICS

- 5.3A** Describe current landscape of investigators (number and demographics) focused on PAD to establish appropriate targets for growth.
- 5.3B** Recruit early-stage investigators to focus on science related to PAD (including basic, clinical and translational science).
- 5.3C** Increase the diversity of investigators (by sex, race and ethnicity) focused on the study of PAD.
- 5.3D** Increase the number of scientific mentors focused on PAD to train and support early-stage investigators.
- 5.3E** Increase the number of career development and training awards to build scientific expertise focused on PAD.
- 5.3F** Increase awareness of existing training and career development funding opportunities for scientific investigation of PAD.

ACTION 5.4: Increase comparative effectiveness research in PAD.

RATIONALE

Since the patient population is mostly heterogeneous, robust evidence is needed for researchers, practitioners and policymakers to understand why and how interventions work in patients with PAD and to anticipate when and for whom they will work and when to adapt interventions to meet the needs of specific subgroups of patients.

Several gaps in our knowledge need to be addressed. First, despite significant risk of adverse cardiovascular and limb events, few trials comparing the relative effectiveness of different therapies to address cardiovascular risk have been completed in patients with PAD without chronic limb-threatening ischemia (CTLI). Second, there is a lack of well-powered comparative effectiveness trials to determine the best medical therapies to improve symptoms and functional status in patients with symptomatic PAD without CTLI. Third, there are large gaps in our knowledge as to the factors that put people with PAD at risk for progression to CTLI.



GOAL 5

TACTICS

- 5.4A** Determine strategic areas of clinical equipoise in order to prioritize multisite randomized clinical trials to compare effectiveness and cost of treatment strategies for PAD and CLTI, and how they improve quality of life for patients.
- 5.4B** Increase funding opportunities to pursue comparative effectiveness trials.
- 5.4C** Develop a clinical trials network that can effectively recruit PAD participants, including populations at high risk through large health systems, such as the Veterans Administration.
- 5.4D** Develop high-quality observational databases, in collaboration with the Vascular Quality Initiative network and others, to facilitate the study of optimal therapeutic strategies for patients with PAD.

ACTION 5.5: Advance research in CLTI.

RATIONALE

While approximately 10% of PAD patients develop chronic limb-threatening ischemia (CLTI), risk factors for disease progression are poorly understood. Patients with CLTI frequently require more resources than those without CLTI due to frequent hospitalization and the need for revascularization and other invasive procedures. Outcomes, such as mortality, morbidity and major amputation, vary by sex, race, ethnicity, socioeconomics and other factors.

Understanding the incidence and prevalence of CLTI across subgroups is important to improve the quality of care, resource allocation and design of interventional studies to reduce systemic and limb-related events. The lack of a longitudinal cohort of PAD patients is a significant barrier to scientific progress. The preclinical and early clinical timeline of PAD can be prolonged, and patients may present with CLTI as their initial PAD diagnosis. It is important to understand both the progression from earlier stages of disease to CLTI as well as the natural history and outcomes of patients from their point of diagnosis with CLTI. The impact of CLTI on patients in terms of quality of life and function needs better characterization. These efforts will also lead to increased public and provider awareness, and support advocacy for national initiatives.

GOAL 5

TACTICS

- 5.5A** Conduct a multidisciplinary workshop to reach consensus on outcome definitions and prioritization of data elements for epidemiological research of CLTI.
- 5.5B** Create funding opportunities to improve understanding of CLTI outcome disparities through longitudinal cohort studies and randomized trials.
- 5.5C** Create public-private partnerships to engage all interested stakeholders and expand capacity for CLTI research.



ACTION 5.6: Leverage data science to expand PAD knowledge and generate research hypotheses.

RATIONALE

Advancing the breadth of science in PAD and improving health for patients calls for collaborative biomedical research and increased public sharing of conventional and “big” data, defined as large and/or complex digital data that are increasingly available through advances in technology such as human genomic sequencing.⁶⁶

Data science combines computer science and statistics⁶⁷ to rapidly analyze and extract information from datasets to reveal patterns, trends and associations that otherwise would not be identifiable by traditional methods.⁶⁸ Big data methods facilitate generation of data-driven hypotheses that may direct future discovery after validation through traditional hypothesis-driven research methods.⁶⁹

Examples of big data sources that may advance research in PAD include datasets from published clinical trials, large observational studies, tissue biorepositories and patient registries of PAD (especially those with diverse ethnic representation, wide age range and adequate representation of women). Datasets may contain information at the molecular, cellular, tissue and organ levels as well as patient-level demographics, clinical course and insurance claims. With growing capacity for investigators to interrogate disparate, complementary datasets and see novel associations, new research ideas will be sparked to advance knowledge about PAD.

GOAL 5

TACTICS

- 5.6A** Promote adherence to FAIR principles of data sharing among PAD researchers.

- 5.6B** Increase outreach to early career investigators to promote the extent and types of data relevant to PAD/CLTI that is available on National Institutes of Health and other computing platforms (e.g., NHLBI BioData Catalyst and NHLBI BioLINCC).

- 5.6C** Host a webinar series that focuses on approaches to clinical research using AI and machine learning to extract anonymized data that contributes to PAD/CLTI study analyses.

- 5.6D** Promote opportunities for secondary and meta-analyses of existing PAD datasets, particularly for clinical trials, through increased access to primary data.



GOAL 6: ADVOCACY

Coordinate PAD **advocacy** efforts to shape national policy and improve health outcomes.

Leads: Aaron W. Aday, MD, MSc and Marc P. Bonaca, MD, MPH

Group Members: Osama A. Ibrahim, MD; Foluso Fakorede, MD; Amy Friedrich-Karnik, MPP; Lucy Guinn; Tyler Hoblitzell, JD; Arash Harzand, MD, MBA



Despite significant strides in our ability to diagnose and treat PAD, awareness of the disease and its symptoms remains poor.^{1,19,21} This lack of awareness further amplifies existing health disparities.⁷⁰ Efforts to improve awareness of PAD have lagged behind those for other cardiovascular diseases. There continues to be a significant opportunity for government health agencies to address these gaps especially where inconsistencies regarding PAD screening and diagnosis have been demonstrated.⁴⁹

Advocacy may be defined as the act or process, often collective, of supporting a cause or proposal. Advocacy is a critical tool for empowering patients, clinicians and scientists and to share their experiences and expertise with decision-makers and, ultimately, to improve health through policy change. These actions may take place at all levels of government (local, state and federal) and across all branches of government (executive, legislative and judicial). The PAD National Action Plan includes several actions to shape policy through administrative actions (e.g., coverage and payment policy), legislative action (e.g., federal funding for research) and other policies (e.g., surgeon general's reports). To enable these actions, it is essential that we engage others in PAD advocacy across all levels and branches of government which, at its fundamental level, provides a voice for those in greatest need.



GOAL 6

ACTION 6.1: Develop resources to train PAD volunteers as advocates.

RATIONALE

In parallel with efforts to increase understanding and awareness of PAD, improving diagnosis and care requires durable public health policy. To achieve this, it is essential to first understand the policymaking processes across various branches of government and at the local, state and federal levels. It's also important to understand best practices in advocacy strategies and tactics to influence and inform those policymakers, and to identify the individuals and organizations that are best suited to implement change (see below). Many policies are set at the local or state, rather than the federal, level.⁷¹

Policy change often relies on personal relationships, often at local levels, that must be developed and nurtured. Also, in many instances, advocacy must rely upon incremental changes. Even small policy changes may have a significant impact on patient lives over time. Most practicing physicians have not had formal training in advocacy, and those who have had such training are more likely to be in primary care specialties.^{72,73} As a result, it is critical that the PAD National Action Plan fill this gap and facilitate effective advocacy by providing educational and reference materials to clinicians, patients, families and others advocating for better PAD care.

INFORMATION NEEDED FOR EFFECTIVE ADVOCACY



Policy Levers

What policy vehicle will best achieve our policy goal?

Does the policy change require legislation?

Does the policy change require regulation?

Is a policy change more suited or better implemented by a public health or research organization?



Details of the Policymaking Process

How are bills introduced, debated, modified and passed into law?

How does this differ at the local, state and federal levels?

What is the regulatory process and what are the opportunities to influence rule-making at the various stages?



Appropriate Setting for Advocacy

Is the ask better suited for the local, state or federal level?

What organizations or committees have the power to implement the ask?



Advocacy Priorities

Does the ask fit in with other current priorities of member organizations?

How can individuals and member organizations use current legislative priorities or debates to further PAD-related advocacy efforts?

GOAL 6

TACTICS

- 6.1A** Collate existing advocacy materials from participating organizations.
- 6.1B** Review existing advocacy materials and create resources to address gaps, including both written materials and scripts for live sessions.
- 6.1C** Obtain feedback from collaborating organizations regarding the new content.



ACTION 6.2: Create a PAD advocacy toolkit.

RATIONALE

When interacting with policymakers and other leaders, advocates need to feel comfortable and confident presenting facts, figures and personal anecdotes for their specific cause.⁷¹ This information needs to be readily available in a central location for advocates. In addition, some of this material needs to be in a format accessible to the layperson so that it can be distributed as handouts following meetings. Several partner organizations already have toolkits with some informational material specific to PAD^{74,75} as well as for general health advocacy.⁷⁶ However, this existing advocacy material could be improved by being more specific to PAD.

TACTICS

- 6.2A** Collect and review existing materials from participating organizations in a centralized online repository.
- 6.2B** Review existing materials and create draft materials, including graphic design mockups.
- 6.2C** Engage member organizations to review the new content and provide critical feedback.

GOAL 6

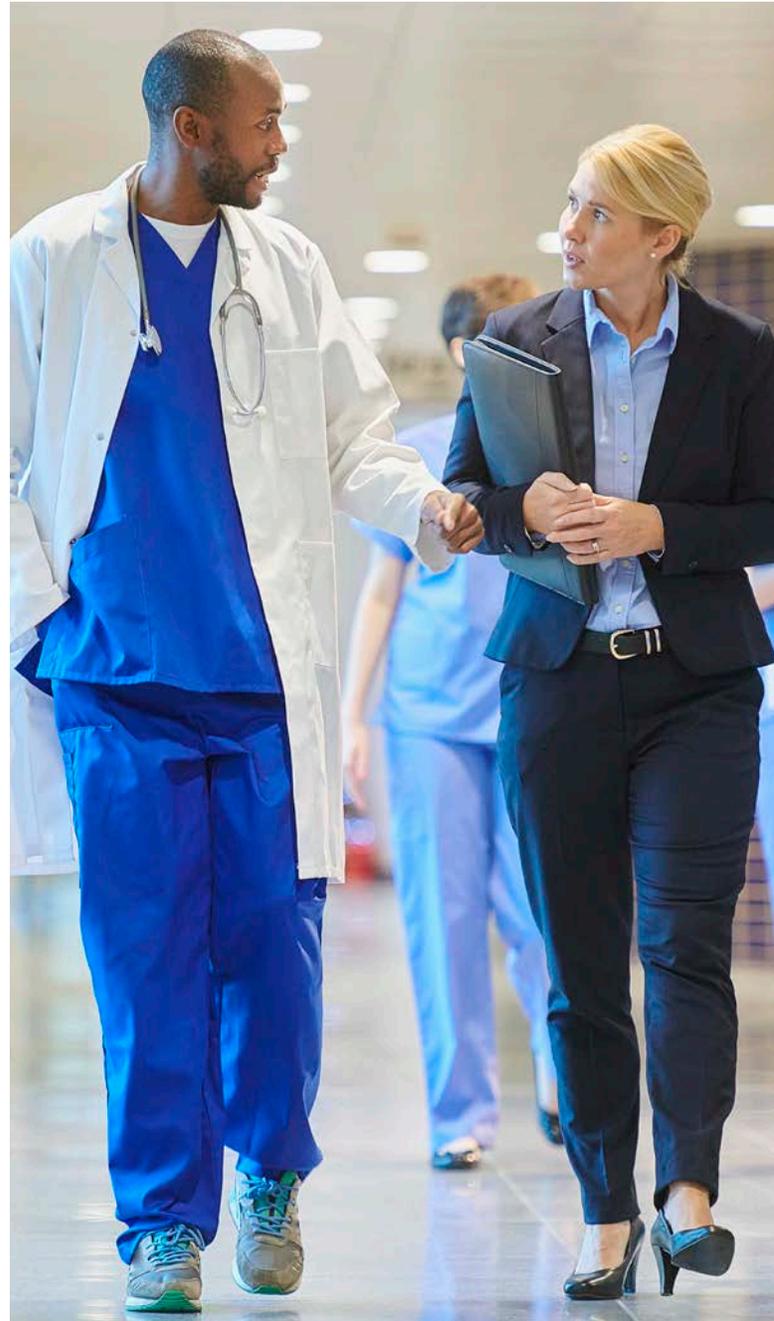
ACTION 6.3: Identify and align with collaborating organizations' advocacy campaigns to further the PAD advocacy agenda.

RATIONALE

Although PAD as a disease state deserves specific awareness efforts, the risk factors for PAD and its impacts are also aligned with other disease awareness and prevention efforts. For example, diabetes is one of the most potent risk factors for PAD, and amputation is a severe complication of diabetes, particularly in patients with comorbid PAD. Therefore, collaborating with groups working on diabetes awareness may enable PAD-specific messaging to be embedded and amplified within those efforts. As a result of PAD expert volunteer engagement, there is significant expertise in the epidemiology, diagnosis, prevention and treatment of PAD, which can be leveraged to help aligned campaigns effectively highlight PAD within their efforts.

TACTICS

- 6.3A** Identify leaders among groups active in related activities (e.g., diabetes care and treatment) and develop a process document along with a list of key opportunities for synergistic activities.
- 6.3B** Develop and collate key opportunities for synergistic advocacy, contacts and timelines.
- 6.3C** Leverage and develop materials to enable rapid collaboration and communication with advocacy partners to ensure alignment of goals.



GOAL 6

ACTION 6.4: Mobilize PAD advocates to influence policymakers in support of a PAD advocacy agenda.

RATIONALE

Although there have been efforts to build awareness of PAD at the federal level both within Congress and the administration, and a PAD Congressional Caucus has been formed, PAD still has lower levels of awareness and understanding compared to other cardiovascular diseases. To realize certain goals, federal legislation will be necessary. In synergy with the previous three action items, a formal PAD “Day on the Hill” could be a way to consolidate messaging and emphasize specific needs among federal policymakers.

TACTICS

- 6.4A** Develop a plan for PAD “Day on the Hill” and coordinate local PAD advocacy efforts.
- 6.4B** Develop materials and engage in training.
- 6.4C** Hold regular meetings with the PAD Congressional Caucus.



Summary of Goals & Actions

1

PUBLIC AWARENESS

Reach people with PAD and those at risk for PAD by **improving public awareness** of PAD symptoms and diagnosis.

- 1.1 Establish a diverse national patient advisory group to identify what information needs to be communicated to address public awareness gaps and how best to communicate it.
- 1.2 Develop messaging to increase awareness of PAD for diverse priority audiences within the general population.
- 1.3 Prioritize the approach to reach at-risk groups for messaging.
- 1.4 Identify partners to amplify consumer awareness initiatives.
- 1.5 Secure funding to launch and sustain PAD consumer awareness initiatives.

2

PROFESSIONAL EDUCATION

Enhance professional education for multidisciplinary health care professionals who care for people with PAD.

- 2.1 Teach professionals how to empower patients with PAD to make and sustain self-care strategies.
- 2.2 Develop and disseminate educational curriculum to multidisciplinary health care professionals.
- 2.3 Promote and disseminate PAD guidelines to multidisciplinary health care professionals.
- 2.4 Increase awareness, detection and screening of patients at risk for PAD through provider engagement.
- 2.5 Provide practice support and improve patient access to guideline-directed medical care.

3

DETECTION & TREATMENT

Activate health care systems to provide enhanced programs for the **detection and treatment** of PAD patients, with a focus on understanding and addressing patient-centered **outcomes**.

- 3.1 Improve PAD detection, treatment and timely referral for revascularization through health system activation.
- 3.2 Develop approaches for patient-centered PAD care.
- 3.3 Establish standards and accreditation for supervised exercise therapy programs.

4

PUBLIC HEALTH

Reduce the rates of nontraumatic lower extremity amputations related to PAD through public outcome reporting and **public health interventions**.

- 4.1 Establish system for public reporting of amputations at the hospital level.
- 4.2 Develop and implement public policy for payment and service delivery model to improve PAD care.
- 4.3 Establish policy priorities for PAD detection in people at high risk for amputation.
- 4.4 Urge expert organizations, government agencies, public organizations and the media to highlight amputation.

5

RESEARCH

Increase and sustain **research** to better understand prevention, diagnosis and treatment of PAD.

- 5.1 Grow basic and translational research in PAD.
- 5.2 Grow clinical research in PAD.
- 5.3 Grow research training and career development in PAD.
- 5.4 Increase comparative effectiveness research in PAD.
- 5.5 Advance research in CLTI.
- 5.6 Leverage data science to expand PAD knowledge and generate research hypotheses.

6

ADVOCACY

Coordinate PAD **advocacy** efforts to shape national policy and improve health outcomes.

- 6.1 Develop resources to train PAD volunteers as advocates.
- 6.2 Create a PAD advocacy toolkit.
- 6.3 Identify and align with collaborating organizations' advocacy campaigns to further the PAD advocacy agenda.
- 6.4 Mobilize PAD advocates to influence policymakers in support of a PAD advocacy agenda.



Leads & Group Members

1

PUBLIC AWARENESS

Reach people with PAD and those at risk for PAD by **improving public awareness** of PAD symptoms and diagnosis.

Leads: Natalie Evans, MD; Sanjay Misra, MD; Stanton B. Shanedling, PhD, MPH

Group Members: Ayanna Buckner, MD, MPH; Lenora E. Johnson, DrPH, MPH; Jeffrey Quinlan, MD; Frank Diaz; Ruth A. Bryant PhD, RN; Susana Gonzalez MHA, RN; Megan D. Patterson, MBS; Lucinda Miner, MD; Geoffrey D. Barnes, MD, MSc; Hank Wasiak, MBA

2

PROFESSIONAL EDUCATION

Enhance professional education for multidisciplinary health care professionals who care for people with PAD.

Leads: Lee Kirksey MD, MBA and Debra Kohlman-Trigoboff, ACNP-BC, CVN

Group Members: Gregory Piazza, MD, MS; Laura Findeiss, MD; Lola Coke, PhD, ACNS-BC; Karen Bauer, DNP, APRN-FNP; Jonathan K. Ehrman, PhD, FAACVPR; Matt Peterson; Steve Hamburger, MBA; Shireen Khoury, MD, MPH; Caitlin Couture, CAE

3

DETECTION & TREATMENT

Activate health care systems to provide enhanced programs for the **detection and treatment** of PAD patients, with a focus on understanding and addressing patient-centered **outcomes**.

Leads: Kim Smolderen, PhD and Scott Damrauer, MD

Group Members: Mark A. Creager, MD; Laurence Sperling, MD; Hillary Johnston-Cox, MD PhD; Kevin Heath, MD, MPH; Wendy Hitchcock, MBA; Luke R. Wilkins, MD; Dean Diersing, MS, FAACVPR; Bernard Dennis, BA; Eduardo Sanchez, MD

4

PUBLIC HEALTH

Reduce the rates of nontraumatic lower extremity amputations related to PAD through public outcome reporting and **public health interventions**.

Leads: J. Antonio Gutierrez, MD, MHS and Kunihiro Matsushita, MD, PhD

Group Members: Josh A. Beckman, MD; Yazan Duwayri, MD, MBA; Aaron Horne, Jr., MD, MHS; Scott Kinlay, MBBS PhD; Dyane E. Tower, DPM, MPH; Christopher J. White, MD; Linda Amos; Barbara Entl, MD

5

RESEARCH

Increase and sustain **research** to better understand prevention, diagnosis and treatment of PAD.

Leads: Peter Henke, MD; Diane Reid, MD; Mary M. McDermott, MD

Group Members: Sue Duval, PhD; Diane Treat-Jacobson, PhD RN; Lyndon Joseph, PhD; David W. Schopfer, MD MAS; Michael Conte, MD; John A. Spertus, MD, MPH; Teresa L. Z. Jones, MD; Susan Ziemann, MD PhD; Cheryl Wilson

6

ADVOCACY

Coordinate PAD **advocacy** efforts to shape national policy and improve health outcomes.

Leads: Aaron W. Aday, MD, MSc and Marc P. Bonaca, MD, MPH

Group Members: Osama A. Ibrahim, MD; Foluso Fakorede, MD; Amy Friedrich-Karnik, MPP; Lucy Guinn; Tyler Hoblitzell, JD; Arash Harzand, MD, MBA

Working Groups Background and Process

Thought leaders from multidisciplinary backgrounds, including patient representatives, were invited to participate in working groups before the April 2021 PAD Summit. Building on the work of the PAD Roundtable in December 2018 at the National Heart, Lung, and Blood Institute, these groups met via telephone or Zoom every two to four weeks to brainstorm proposed action items for each of the six strategic goals. Each group of approximately 10 people had two or three leaders who moderated the group discussion and drafted the proposed elements of their specific goal area. The preliminary recommendations were presented to the advisory committee, revised and then shared during the PAD Summit with real-time feedback from the participants.



Collaborating Organizations

The following organizations participated in the April 2021 PAD Summit and contributed to the development of the PAD National Action Plan. Organizational contribution does not indicate endorsement.

American Academy of Family Physicians

American Association of Cardiovascular and Pulmonary Rehabilitation

American College of Cardiology

American Diabetes Association

American Heart Association

American Podiatric Medical Association

Association for the Advancement of Wound Care

Association of Black Cardiologists

Centers for Disease Control & Prevention

Centers for Medicare & Medicaid Services

National Association of Community Health Centers

National Heart, Lung, and Blood Institute

National Hispanic Nurses Association

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute on Aging

Optum

Patient-Centered Outcomes Research Institute

Preventative Cardiovascular Nurses Association

Society for Cardiovascular Angiography & Interventions

Society for Vascular Surgery

Society of Interventional Radiology

Society for Vascular Medicine

Society for Vascular Nursing

Vascular Cures

VIVA Foundation

WomenHeart

Glossary

ACRONYM

MEANING

ABI	ankle-brachial index
ACC	American College of Cardiology
AHA	American Heart Association
CAD	coronary artery disease
CME	continuing medical education
CTLI	chronic limb-threatening ischemia
FAIR	findability, accessibility, interoperability and reusability
IC	intermittent claudication
NHLBI	National Heart, Lung, and Blood Institute
PAD	peripheral artery disease
PAG	patient advisory group
SET	supervised exercise therapy



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